

# **EXHIBIT 6**

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS**

DePuy Mitek, Inc. )  
a Massachusetts Corporation )  
Plaintiff, )  
v. ) Civil No. 04-12457 PBS  
Arthrex, Inc. )  
a Delaware Corporation and )  
Pearsalls Ltd., )  
a Private Limited Company )  
of the United Kingdom, )  
Defendants. )

**Declaration of Dr. David Brookstein In Support of DePuy Mitek's  
Claim Interpretation of the Hunter Patent and Summary Judgment of Infringement**

**I. Background Information**

**A. Teaching Experience**

1. I am the Dean and Professor of Engineering at the School of Engineering and Textiles of Philadelphia University. I have held this position since 1994. In 2005, I also was appointed Executive Director of Research at Philadelphia University.
2. I was a Visiting Scholar at the Harvard University Center for Textile and Apparel Research (Division of Engineering and Applied Sciences) between 2002-2003.
3. I was an Adjunct Professor in Mechanical Engineering at Northeastern University in Boston, MA from 1981-1983. At Northeastern, I taught undergraduate courses in statics, dynamics, and mechanics of deformable bodies and material science.
4. I was Assistant Professor of Textile Engineering at Georgia Institute of Technology, College of Engineering from 1975 – 1980. At Georgia Tech, I taught and conducted research in

the fields of textile and composites engineering with special emphasis on improving the energy efficiency of manufacturing systems.

**B. Work Experience**

5. From 1980 to 1994, I worked at Albany International Research Co. At Albany International Research, I was an Associate Director from 1992 to 1994. From 1983 to 1992, I was an Assistant Director. From 1980 to 1982, I was a Senior Research Associate. While at Albany International Research Co., I directed all activities of the professional engineering group and was responsible for contract research, development, and manufacture of advanced composite materials and technical polymeric materials. My accomplishments include the invention and development of the multilayer interlock braiding system for producing three-dimensionally reinforced fibrous performs for aerospace structures, the development of implantable biomedical devices such as vascular prostheses and orthopedic implants and the development of unique textile-based civil engineering structures.

**C. Education**

6. I have a Doctor of Science in the field of Mechanical Engineering, Minor Studies in Management from Sloan School of Management, Massachusetts Institute of Technology, 1976.

7. I have a Master of Science in Textile Technology from M.I.T., 1973.

8. I also hold a Bachelor of Textile Engineering, from Georgia Tech, 1971.

9. I also attended the Harvard Business School Summer Program on Research Management in 1990 and the Harvard Graduate School of Education MLE Summer Program, 1998.

10. When I was a researcher at Albany International Research Co., in the late 1980's, I led a program that involved the development of braided sutures for a commercial client. While at Albany, I researched, developed, tested and evaluated numerous braided and woven biomedical implants, including woven ACL prosthesis, braided artificial arteries, and textile-based,

resorbable bone plates and screws. Furthermore, I have taught textile engineers at the undergraduate and graduate level at Philadelphia University materials that involve the design, construction, braiding, manufacturing, and processing of textile structures that includes braids. Specifically, among other things, I have taught courses in Fiber Science which include fiber and yarn tensile, bending, and compression properties. Additionally, I was awarded the TechTextil Innovation Prize (Germany) in 1993 for my work in braiding.

11. My publications and patents for which I am an inventor are listed in my curriculum vitae (Ex. 1).

12. I have been asked to prepare this declaration based on my prior reports, deposition testimony, and Arthrex's motion for summary judgment. This declaration is basically my prior opinions reformatted to address the issues that I have been asked to address.<sup>1</sup>

## **II. Legal Framework of My Opinions**

13. I understand that the statutory basis for a determination of direct patent infringement is set forth in 35 U.S.C. §271(a) which states:

Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any Patented invention, within the United States or imports into the United States any Patented invention during the term of the Patent therefore, infringes the Patent.

14. I understand that an analysis of direct infringement requires two steps. First, the Court determines the meaning of the claims. Then, the properly construed claims are applied to a product to determine whether it infringes the Patent. I understand there are two types of direct infringement -- literal infringement and infringement under the doctrine of equivalents.

15. Infringement is "literal" when each claim limitation is literally present in a device. I understand that even if a device does not literally have each claim limitation, there is still

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<sup>1</sup> For purposes of this declaration, I use the term FiberWire to refer to Arthrex's FiberWire and TigerWire's products except where noted.

infringement if the device has an equivalent of the claimed limitation that is not literally present.

I understand that one method for determining whether a structure is equivalent to a claim limitation is the insubstantial differences test. Under this test, if the differences between the structure and the claim element are insubstantial, then they are equivalent. One method for determining whether the differences are insubstantial is whether the structure in the accused device “performs substantially the same function in substantially the same way to obtain the same result” (“function/way/result test”) as the claimed element.

**III. If “General Purpose PE” Is Deemed Not To Literally Include FiberWire’s Braided PE, Then FiberWire Infringes Under the Doctrine of Equivalents**

**A. The Differences Between FiberWire’s PE and the Claimed First Fiber-Forming Materials Are Insubstantial**

16. If “PE” as claimed in the 446 Patent is construed to mean “general purpose PE” (Arthrex Brf. on Claim Construction at 10, hereinafter “Arthrex Br.”), and it is found that FiberWire’s braided PE is not literally “general purpose PE,” then it is my opinion that there is infringement under the doctrine of equivalents because the differences between FiberWire’s braided PE and the first fiber-forming materials are insubstantial.

17. In a preferred embodiment, the 446 Patent describes the first fiber-forming materials as acting “as lubricating yarns” (Ex. 2 at 4:11-12). PE, including UHMWPE, is a lubricious material (Ex. 3 at 52:24-53:1). Further, the 446 Patent explains that the first set of yarns may be “non-absorbable polymers” (Ex. 2 at 4:10-11). UHMWPE is a non-absorbable polymer. The 446 Patent also describes the first set of yarns as being made from fiber-forming materials (Ex. 2 at 2:45-46). UHMWPE is a fiber-forming material. Therefore, the 446 Patent’s description of the first-fiber forming materials is consistent with UHMWPE. Moreover, UHMWPE is consistent with the more general description of the invention, as set forth in column 2, lines 40-63, column 3, lines, 21-28, 40-65, and column 6, lines 50-56.

18. My opinion is supported by Mr. Grafton's testimony regarding the development of FiberWire and by Arthrex's 234 patent. As Mr. Grafton explained, he had developed a suture having a homogeneous braid of UHMWPE (Ex. 3 at 51:15-17). But he found this UHMWPE braid to be unacceptable because it had poor knot holding strength properties (*id.* at 51:15-53:7). As Mr. Grafton explained, the poor knot holding strength properties were attributable to UHMWPE being a lubricous material, which causes the knot to slip (*id.* at 52:24-53:7). To increase the knot holding strength, Mr. Grafton braided UHMWPE with PET (*id.* at 53:20-54:5; 46:16-47:5). Mr. Grafton tested the UHMWPE and PET braid and found that it had improved knot holding strength properties as compared to the UHMWPE braid (*i.e.*, the heterogeneous braid did not slip like the homogeneous UHMWPE braid) (*id.* at 54:24-55:1). This type of UHMWPE and PET braid ultimately became FiberWire. Thus, as Mr. Grafton's experience shows, FiberWire is a braid of UHMWPE (a lubricous yarn) with PET, and the PET increases the knot holding strength of the braid. This just like the 446 Patent because the 446 Patent describes embodiments in which the first fiber-forming materials are lubricous and the second fiber-forming materials impart strength. Accordingly, FiberWire's braid is not, as Arthrex has suggested, the opposite of what is described in the 446 Patent.

19. Arthrex's 234 Patent also supports my opinion. According to Mr. Grafton's 234 Patent, UHMWPE, "while much stronger than ordinary surgical suture, does not have acceptable knot tie down characteristics for use in surgical applications" (Ex. 4 at 1:19-21; Ex. 3 at 104:9-15). Mr. Grafton defines knot tie down as a strength, namely the "ability to approximate the tissue and hold [tissue] in place through biomechanical forces" in the body (Ex. 3 at 26:24-27:6). Mr. Grafton's definition of knot tie down is part of what I refer to as knot holding strength. According to Arthrex's 234 patent, this problem was overcome by braiding UHMWPE with

polyester (Ex. 4 at 2:50-57). As the 234 patent explains, braiding polyester with UHMWPE improves knot tie down characteristics or the “ability to approximate the tissue and hold it in place through biomechanical forces” (Ex. 3 at 26:24-27:10). Thus, the 234 patent teaches that polyester, which includes materials such as PET, imparts knot tie down or knot holding strength to a braid of UHMWPE and polyester. Thus, Arthrex’s 234 Patent further shows that the differences are insubstantial because UHMWPE is described as a lubricous yarn that with bad knot properties, and similarly embodiments of the first fiber-forming materials are described as lubricous.

20. I understand that Arthrex has asserted that the differences between the first fiber-forming materials (if PE does not include UHMWPE) and UHMWPE are substantial because the purpose of UHMWPE in FiberWire is alleged to be to provide strength (Arthrex Br. at 11). I disagree with this statement because the 446 Patent describes embodiments in which the first set of yarns is lubricous and provides PE as an example of a lubricous yarn (Ex. 2 at 4:11-12). The UHMW PE in FiberWire is consistent with this description; FiberWire’s UHMW PE is lubricous (Ex. 3 at 52:24-53:1). The 446 Patent also describes embodiments in which the claimed second fiber-forming yarns, including PET, are braided with the claimed first fiber-forming lubricous yarns, including PE, “to provide improved strength to the heterogeneous braid” (Ex. 2 at 4:33-36). FiberWire is consistent with this description; FiberWire’s PET has a different lubricity than UHMWPE and adds improved strength to the FiberWire braid (Ex. 3 at 53:20-54:5; 46:16-47:5). Accordingly, PET increases certain knot strength properties, namely knot holding strength,<sup>2</sup> of

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<sup>2</sup> I use the term “knot pull strength” to refer to the force at which a suture having a knot tied in it fails when tested in a tension test. I use the term “knot holding strength” to refer to the force at which a knot fails by slipping, elongating to a certain extent, or breaking, which can be tested generally in a procedure similar to Exs. 26 and 27. Knot holding strength is an indication

the braid of PET and UHMWPE because it reduces the tendency of the UHMWPE fibers to slip when tied in a knot. Thus, because FiberWire's UHMWPE is lubricous and FiberWire's PET imparts strength, FiberWire's construction is not the opposite of that described and claimed in the 446 Patent. Rather, it is consistent with the 446 Patent's teachings.

**B. The Differences Between the Claimed First Fiber-Forming Materials And FiberWire's PE Are Insubstantial Based On the Function/Way/Result Analysis**

21. It is my opinion that all of Arthrex's FiberWire™ and TigerWire™ suture products also infringe claims 1, 2, 8, 9, and 12 of the '446 Patent under the doctrine of equivalents because the differences, if any, between the claims, as I understand they may be construed by Arthrex, and Arthrex's FiberWire™ and TigerWire™ suture products are insubstantial under the function/way/result analysis.

22. I have used the "function/way/result" test to determine infringement of claims 1, 2, 8, 9, and 12 under the doctrine of equivalents. In particular, I have determined the function/way/result of the claim element that Arthrex contends is not literally satisfied and compared that to the function/way/result of UHMWPE in FiberWire™ and TigerWire™. My equivalency opinion is limited to nonbioabsorbable yarns as the first-forming material.

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of knot security. The 446 Patent describes another exemplary knot security test (Ex. 2 at 6:36-44).

23. In my opinion, the “function” of the first fiber-forming material is the same as the function of UHMWPE in Arthrex’s FiberWire™ and TigerWire™ suture products:

<b>Claims 1, 2, 8, 9, and 12 Limitation</b>	<b>Function of Limitation Under the Doctrine of Equivalents</b>	<b>Function of UHMWPE in FiberWire™ and TigerWire™ Suture Products</b>
a) each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material selected from the group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and PE; and	The function of the first set of yarns is to contribute a property that is different than a yarn from the second set.	UHMWPE contributes different lubricity and strength properties to the heterogeneous braid than PET.

24. My opinion regarding the “function” of the first fiber-forming material is supported by the ‘446 Patent. The ‘446 Patent explains that the first fiber forming material is “dissimilar” to the second fiber and the braid of dissimilar yarns provides “outstanding properties attributable to the specific properties of the dissimilar fiber-forming materials which make up the braided yarns” (Ex. 2 at 2:50-52; 3:43-48). Further, the ‘446 Patent explains that it is possible to “tailor the physical” properties by “varying the type and proportion of each of the dissimilar fiber forming materials used” (*id.* at 2:58-61). Also, the patent notes that the different fiber components make different relative contributions to one or more properties of the heterogeneous braid (*id.* at 8:19-21).

25. It is my opinion that the UHMWPE in Arthrex’s FiberWire™ and TigerWire™ products has the function as the claimed first fiber-forming material based on an examination of FiberWire™ and TigerWire™ and its manufacturing. In my opinion, the UHMWPE contributes a property or properties that is/are different from the property or properties contributed by the PET. For example, Mr. Hallet testified that, in the development of FiberWire™, he had constructed a 100% homogeneous UHMWPE braid, but Arthrex had requested a less stiff braid.

Mr. Hallet then made a heterogeneous braid of UHMWPE and PET to get the strength of UHMWPE and the flexibility of PET (Ex. 5 at 306:17-307:14; Ex. 6; *see also* Ex. 5 at 307:15-308:14; Ex. 7). Further, as I explained in my rebuttal report with respect to Mr. Grafton's work and Arthrex's 234 Patent, FiberWire's PE also provides lubricity and other surface properties that are different than PET, and PET when braided with PE in FiberWire increases the knot holding strength.

26. In my opinion, the "way" of the first fiber-forming material is the same as the "way" of UHMWPE in Arthrex's FiberWire<sup>TM</sup> and TigerWire<sup>TM</sup> suture products:

<b>Claims 1, 2, 8, 9, and 12 Limitation</b>	<b>"Way" of Limitation Under the Doctrine of Equivalents</b>	<b>Way UHMWPE performs its Function in FiberWire<sup>TM</sup> and TigerWire<sup>TM</sup></b>
a) each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material selected from the group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and PE; and	The "way" is at least one yarn from the first set of yarns is in direct intertwining contact with at least one yarn from the second set.	At least one UHMWPE yarn is braided with at least one PET yarn in direct intertwining contact (Ex. 8 at 99-107).

27. My opinion regarding the "way" of the "first fiber-forming" element is supported by the '446 Patent. The '446 Patent explains that the way that the first-fiber forming material performs its function is by braiding it with a second dissimilar yarn in direct intertwining contact. For example, the '446 Patent states in the "Summary of the Invention" section that the "the invention is a heterogeneous braid comprising a first and second set of discrete yarns in a sterilized, braided construction" and that the at least one yarn from the first set is in "direct intertwining contact" with a yarn from the second set (Ex. 2 at 2:40-44; *see also* 3:21-28; 3:40-45). The '446 Patent further explains that the heterogeneous braid properties are due to the "mechanical interlocking or weaving of the individual yarns" (*id.* at 2:56-58; 3:43-48). Also, during the

prosecution history, the applicants explained that the beneficial properties are due to the braiding of direct “intertwining” contact of dissimilar yarns (Ex. 9 at 2, emphasis original).

28. Further, the ‘446 Patent describes certain preferred embodiments in which the first fiber-forming materials act as lubricating yarns and the second fiber-forming materials provide strength (Ex. 2 at 4:9-59). The ‘446 Patent also describes other specific preferred embodiments that have PTFE braided in direct intertwining contact with PET to obtain the benefits of each yarn (*id.* at 7:1-8:61). These are all preferred embodiments where the at least one first-fiber forming material is braided in direct intertwining contact with at least one different, second fiber-forming material so that each yarn contributes to the heterogeneous braid. Because these are preferred embodiments, they are an example of the broader disclosed concept of braiding the first and second fiber forming materials, so that they can individually contribute to the overall properties of the heterogeneous braid. Notably, the invention is described more broadly than just these “preferred embodiments,” and, therefore, it is my opinion that neither the function, way, or result is limited to the specific properties of the first-forming material in any of the preferred embodiments.

29. It is my opinion that the UHMWPE in Arthrex’s FiberWire™ and TigerWire™ suture products have the same “way” as the claimed first-fiber forming materials. My opinion is based on a visual inspection and observation of FiberWire™ and its manufacturing processes. In my opinion, at least one UHMWPE yarn in Arthrex’s FiberWire™ and TigerWire™ products is braided in direct intertwining contact with at least one PET yarn. My opinion is supported by Arthrex’s and Pearsalls’ testimony and documents. For example, Mr. Dreyfuss testified that the adjacent yarns in the FiberWire™ and TigerWire™ sheath are in direct intertwining contact with each other (Ex. 8 at p. 99-107).

30. In my opinion, the “result” of the first forming material is the same as the result of UHMWPE in Arthrex’s FiberWire™ and TigerWire™ suture products:

<b>Claims 1, 2, 8, 9, and 12 Limitation</b>	<b>“Result” of Limitation Under the Doctrine of Equivalents</b>	<b>Result of UHMWPE in FiberWire™</b>
a) each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material selected from the group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and PE; and	The result of the first set of yarns is to contribute to the heterogeneous suture braid a property different from the yarn in the second set, so that when they are braided the yarns contribute to the properties of the overall heterogeneous braid.	The result of the PE yarns is to provide a different property than the PET, so that when they are braided the PE yarns contribute properties to the overall heterogeneous braid.

31. My opinion regarding the “result” of the first-forming material is supported by the ‘446 Patent. For example, the ‘446 Patent explains that the “heterogeneous braids may exhibit a combination of outstanding properties attributable to the specific properties of the dissimilar fiber-forming materials” (Ex. 2 at 2:49-52). Further, the ‘446 Patent states that the “types of yarns used to prepare the heterogeneous braid and the yarn geometry can be varied to prepare heterogeneous braids within the scope of the claimed invention which exhibit a combination of outstanding physical or biological properties.” (*id.* at 6:52-56).

32. My opinion is that FiberWire™ and TigerWire™ suture products have the same claimed result. UHMWPE has and contributes properties that are different from those provided by PET. For example, Arthrex has admitted that the UHMWPE is added to FiberWire™ to increase strength. In FiberWire™, when the UHMWPE is braided with PET, it is my opinion that the UHMWPE contributes to the strength of the overall heterogeneous braid. Further, UHMWPE is known to have relatively high lubricity and has different lubricity than PET. Also, as I explained in my rebuttal report and through my declaration with reference to Arthrex’s 234 Patent, Mr.

Graftons' work, and the development of FiberWire, UHMWPE adds lubricity, pliability, and surface properties that are different than PET.

33. My opinion is further supported by the testimony and documents from Arthrex and Pearsalls witnesses:

Q What did you understand Mr. Grafton to mean when he said:

"Can you build a 25% Dyneema/75% polyester blend in Size 2 that is very flexible". What did you understand that to mean?

A Yes, that he wanted a braid which was more -- not so stiff.

Q As the 100% ultra high molecular weight polyethylene?

A Yes. (Ex. 5 at 306:20-307:4, Ex. 6)

Q. Mr. Grafton wanted Pearsalls to braid polyester with the ultra high molecular weight polyethylene so that the polyester could provide flexibility?

A Yes. (Ex. 5 at 307:10-14, Ex. 6).

34. It is my expert opinion that both of the above documents and testimony demonstrate that Arthrex is "tailor[ing] the physical" properties of the braid by "varying the type and proportion of each of the dissimilar fiber forming materials used" as taught by the '446 Patent (Ex. 2 at 2:58-61).

**C. I Disagree With Arthrex's Assertions Regarding the Purpose & Function of the First Fiber-Forming Materials**

**1. The 446 Patent Does Not State that the Only Function of the First Fiber-Forming Materials Is to Improve Pliability**

35. I disagree with Arthrex's assertion that the only function of the first fiber-forming materials described in the 446 Patent is improving pliability. As I explained in my first report at ¶55 and my rebuttal report at ¶10, the 446 Patent describes a broader function for the first fiber-forming materials that is not limited:

- “heterogeneous braids may exhibit a combination of outstanding properties attributable to the specific properties of the dissimilar fiber-forming materials which makeup the yarns” (*id.* at 2:49-52);
- “it is possible to tailor the physical . . . properties of the braid by varying the type and proportion of each of the dissimilar fiber forming used” (*id.* at 2:58-62);
- in preferred embodiments the first fiber-forming materials can contribute other properties including “pliability,” “compliance” and “surface lubricity” (*id.* at 4:11-13).

As I explained above, the properties of the first fiber forming materials are much broader than just pliability.

## 2. The 446 Patent Does Not Describe the First Fiber-Forming Materials As “Relatively Weak”

36. I disagree with Arthrex’s assertion that the 446 Patent describes the first fiber-forming materials as “relatively weak,” (Arthrex Br. at 11) and that this is a basis for finding that the differences between the first fiber-forming materials and FiberWire’s braided PE are substantial. I disagree because the 446 Patent does not describe the first fiber-forming materials as “relatively weak.” For example, the 446 Patent describes PE, which includes UHMWPE, as a first fiber-forming material, and UHMWPE was known to have certain strength attributes, such as tensile strength. Likewise, the 446 Patent describes polypropylene (PP) as a first fiber-forming material, and it is known to have certain strength attributes, namely tensile strength. This is described in the literature. For example, *Marks’ Standard Handbook for Mechanical Engineers*, a well known reference, describes polypropylene fibers as having a breaking tenacity of 4.0-7.0 gpd (Ex. 10). Further, U.S. Patent No. 4,413,110 describes certain polypropylene fibers as having a tenacity of at least about 8 gpd (Ex. 11 at 2:7-11). Also, the *Production and Applications of Polypropylene Textiles* states on page 54 that the breaking tenacity of polypropylene fibers is over 500 mNtex<sup>-1</sup> (Ex. 12). Thus, certain polyethylene and polypropylene fibers are not “weak”

in tensile strength. Thus, I disagree that the 446 Patent describes the first-fiber forming materials as being “weak.”

37. Arthrex seems to indicate that the first fiber-forming materials are all necessarily “weak” in tension when compared to the second fiber-forming materials and that only the second set of yarns can impart strength (Arthrex Br. at 11). Even assuming that Arthrex means weak in tension, I disagree with this statement. Arthrex’s statement is incorrect because polypropylene fibers, one of the first fiber-forming fibers, were known to have strength on the same order of magnitude of nylon and PET fibers, two of the second fiber-forming materials. For example, *Marks’ Handbook* describes polyester fibers, which I read as including PET, as having a breaking tenacity of 4.4-7.8 gpd, and nylon 6,6 fibers as having a breaking tenacity of 4.6-9.2 gpd (Ex. 10). Further, the *Production and Applications of Polypropylene Textiles* states on page 54 states that the breaking tenacity of polyester fibers, which I read as including PET, is 350 mNtex<sup>-1</sup> (Ex. 12). Using this information, PP has a breaking tenacity in the range of other well known relatively high-strength fibers such as polyester (PET) and nylon. Further, one fiber manufacturer describes the tensile strength of two first fiber-forming materials, PVDF and PP, as having about the same tensile strength as two of the second fiber-forming materials, nylon and PET. For example, it states that monofilament PVDF has a tenacity of 4.71 gpd, two monofilament polypropylenes have breaking strengths of 3.0 and 4.0 gpd, two monofilament polyesters (which I read as PET) as having a breaking strength of 4.5 or 6.0 gpd, and nylon monofilaments as having a breaking strength of 4.5-6 gpd (Ex. 13; *see also* Ex. 14). Consequently, the first fiber-forming materials are not all “weak” in tension in comparison to the second fiber-forming yarns, and it would be incorrect to read the 446 Patent as stating that only the second set of yarns imparts tensile strength, as Arthrex incorrectly suggests.

38. I understand that Arthrex asserts that “the admitted purpose of UHMWPE in FiberWire is to add strength to the braid” and implied that is UHMWPE’s only function (Arthrex Br. at 11). I disagree with this assertion because it is an oversimplification and a misunderstanding of the many different properties that a material can provide. As I explained in my rebuttal report at ¶¶24-27 and here above at ¶17, FiberWire’s PE is lubricous, and therefore it enhances other FiberWire properties such as handleability, pliability, and surface properties. Arthrex’s argument seems to attribute all of FiberWire’s strength to FiberWire’s PE. I disagree with this assumption. FiberWire’s PET also contributes to FiberWire’s strength properties, including knot holding strength properties (Ex. 4 at 1:24-26, 29; 2:50-52; Ex. 3 at 103:19-104:15). Further, even if FiberWire’s PE’s only function is to add tensile strength as Arthrex incorrectly asserts, it is my opinion that the first fiber-forming materials, such as PP and PVDF, function to add tensile strength. Therefore, the differences between UHMWPE and the first fiber-forming materials are insubstantial.

39. Also, Arthrex’s assertion that Ultra high molecular weight PE is “strong” is a simplification of material properties. Ultra high molecular weight PE is “weak” in at least two ways, compression and knot holding properties when braided in certain structures, which I explained above with reference to Mr. Grafton’s work and Arthrex’s 234 Patent. Thus, even if Arthrex is correct (which it is not) that the 446 Patent describes the first fiber-forming materials as “weak” and braids made from them as weak, ultra high molecular weight PE satisfies these requirements because it too is “weak.”

**D. Even if Arthrex is Correct Regarding the Teachings Of the 446 Patent, There Is Still Infringement Under the Doctrine of Equivalents**

**1. Even if Arthrex is Correct That The Function of the First Fiber-Forming Materials Is To Improve Pliability, FiberWire Infringes Because FiberWire's PE Improves Suture Pliability**

40. I understand that Arthrex asserts that the only function of the first fiber-forming materials is to “improve overall pliability of the suture” and FiberWire’s PE does not perform this function because it is a stiff material (Arthrex Br. at 10). For the reasons stated above, I disagree that this is the function of the first fiber-forming materials. But even accepting this function, there is still infringement under the doctrine of equivalents because FiberWire’s braided ultra high molecular weight PE improves overall pliability of the suture. As I explained in ¶25 of my rebuttal report, ultra high molecular weight PE is lubricous and contributes to braid pliability because it allows the fibers to slide past each other when bent. In constructing FiberWire, Arthrex engineered a braid of UHMWPE and PET to maximize the benefits of the dissimilar yarns (Ex. 3 at 68:25-70:12). For example, UHMWPE in FiberWire’s braid contributes to the braid’s tensile strength, knot pull strength, pliability, and lubricity/handling, and PET contributes to the braid’s knot holding strength, and handling/pliability. Thus, Arthrex designed FiberWire to be a braid of dissimilar yarns that has improved handleability and pliability performance without significantly sacrificing physical properties. UHMWPE has many uses. “General purpose” PE and UHMWPE can be substituted for each other, depending on the application.

41. Arthrex’s argument appears to be based on confusing two discrete concepts, *material* stiffness and *braid* stiffness. *Material stiffness* is a material property that is dependent upon just the material properties, like the tensile and compressive modulii, and cross-sectional shape of the specimen, which in this instance is a fiber. In contrast, *braid stiffness* for a multifilament

structure like FiberWire is dependent upon many factors including the number of filaments, the modulus of elasticity in tension and compression, the fiber-to-fiber mobility, and the individual moment of inertia of each filament, the manner in which the materials are braided, and material lubricity. As the 446 Patent explains, material lubricity permits fiber-to-fiber mobility, so that when the braid is bent the fibers can easily bend and slide past other fibers. Thus, even accepting that ultra high molecular weight PE is “stiff,” Arthrex’s counsel assertions that it does not improve overall braid pliability are just wrong.

42. Arthrex’s argument is basically the same concept that I addressed before when Arthrex’s expert incorrectly assumed that FiberWire is a monofilament structure. As I explained previously, FiberWire is neither a monofilament nor a pure multifilament structure. Arthrex’s statement that FiberWire’s PE does not improve braid pliability basically makes a similar mistake and incorrectly assumes that FiberWire is a monofilament type structure.

#### **IV. Under Arthrex’s Definition of “Consisting Essentially Of,” FiberWire Infringes Claims 1, 2, 8, 9, and 12 of the 446 Patent**

43. As I understand the law, because the 446 Patent claims recite the phrase “consisting essentially of,” if FiberWire has structure in addition to the structure listed in the 446 Patent claims, there is infringement, unless the additional structure materially affects the “basic and novel characteristics” of the claimed suture. I understand that Arthrex contends that the “basic and novel characteristics” of the suture claimed in the 446 Patent are “a suture having two dissimilar yarns braided together to achieve improved handleability and pliability performance without significantly sacrificing its physical properties” (Arthrex Br. at 13). Arthrex asserts that that FiberWire’s coating materially affects this novel and basic characteristic because it materially affects handleability and knot tie down properties (Arthrex Br. at 13-14). I disagree for the following three reasons: (i) FiberWire was specifically engineered to have the properties

described in the 446 Patent; (ii) the 446 Patent does not consider coating of the type used on FiberWire to have a “material” affect on the basic and novel characteristics; and (iii) Dr. Burks’ tests and analyses show that FiberWire’s coating does not materially affect handleability. I describe each of these three points below.

**1. FiberWire Was Engineered to Have The Basic and Novel Characteristics, and the Coating Does Not Materially Affect Them**

44. FiberWire’s coating does not materially affect FiberWire’s characteristics of having two dissimilar yarns (*i.e.*, UHMWPE and PET) braided together to achieve improved handleability and pliability performance without significantly sacrificing physical properties. Both before and after the coating is applied to FiberWire, FiberWire has two dissimilar yarns (*i.e.*, UHMWPE and PET). Further, regardless of the coating, the UHMWPE and PET braid provides improved handleability and pliability performance without significantly sacrificing physical properties. The coating does not prevent or materially affect the two materials from being dissimilar, from being braided, or from forming a braid with improved handleability and pliability performance without significantly sacrificing physical properties. In other words because FiberWire still obtains the handleability/physical property benefits of the UHMWPE/PET braid after the coating is applied, the coating does not materially affect the novel and basic characteristics. FiberWire’s coating is merely a surface “lubricant” (Ex. 15).

45. My opinion that FiberWire’s coating does not materially affect FiberWire’s PET and UHMWPE yarns from being dissimilar, from being braided, or from forming a braid with improved handleability and pliability performance without significantly sacrificing physical properties is supported by Arthrex’s development and testing of FiberWire. Arthrex and Pearsalls had originally developed a suture having a homogeneous 100% UHMWPE braid. But they found it to have unacceptable knot holding strength properties (Ex. 3 at 52:24-53:7). The

homogeneous UHMWPE braid was too lubricous to “hold a knot” (*id.* at 45:16-46:15; 50:1-53:7). At the same time, Arthrex found that the same braided UHMWPE suture had other good “strength” properties (Ex. 3 at 46:7-8). I consulted with Dr. Hermes and, based on his opinion and because UHMWPE fibers are lubricous (*id.* at 52:24-53:1), the UHMWPE braid would also have had some good handling properties including surface frictional properties, such as tactile feel. Also, the lubricous yarns would contribute to braid pliability because they allow the fibers to slide past each other when bent. Arthrex and Pearsalls also developed sutures having homogeneous polyester braids (Ex. 16). According to Mr. Grafton, Arthrex found them to have lower knot pull strength than a braid of UHMWPE fibers and polyester fibers (Ex. 16; Ex. 3 at 81:8-12). Thus, Arthrex thought that sutures having braids of UHMWPE and braids of polyester each had different drawbacks. Ultimately, Mr. Grafton braided UHMWPE with PET, which is a polyester, and found that the heterogeneous braid had improved knot holding strength properties; it did not slip like the UHMWPE braid he had made:

- Q. And was the knot slippage of this ultra-high molecular weight polyethylene poor security because of the lubricity of polyethylene?
- A. Yes.
- Q. Yes?
- A. Yes.
- Q. So then you came up with the idea to braid PET with the ultra-high molecular weight polyethylene to reduce the knot slippage?
- A. Yes.
- Q. And when you say knot slippage, we're referring to this knot security test?
- A. Yes.
- Q. So are we using the terms knot slippage and knot security interchangeably here?
- A. You are, yes.
- Q. In your testimony?
- A. Yes.
- Q. So the knot security of the 100 percent ultra-high molecular weight polyethylene was poor, the

prototype; right?

A. Yes.

Q. And your idea was to add the PET and to improve the knot security?

A. I've lost count, it's been so many times, but the answer again is yes.

(Ex. 3 at 53:2-54:5) (objections omitted). This type of UHMWPE and PET braid was ultimately marketed as FiberWire. Thus, Arthrex engineered a braid of UHMWPE and PET to maximize the benefits of the dissimilar yarns (Ex. 3 at 68:25-70:12). For example, UHMWPE in FiberWire's braid contributes to the braid's tensile strength, knot pull strength, pliability, and lubricity/handling, and PET contributes to the braid's knot holding strength, and handling/pliability. Thus, Arthrex designed FiberWire to be a braid of dissimilar yarns that has improved handleability and pliability performance without significantly sacrificing physical properties. Although FiberWire is coated, it is still a braid of dissimilar yarns having these benefits. Although the coating may enhance certain suture properties, the coating does not materially affect the fact that FiberWire has a braid with improved handleability and pliability performance without significantly sacrificing physical properties.

46. My opinion that FiberWire was specifically designed to have the novel and basic characteristics that Dr. Mukherjee attributes to the 446 Patent is further supported by other aspects of FiberWire's development. For example, during FiberWire's initial development, Mr. Grafton asked Pearsalls to "build a 25% Dyneema/75% polyester *blend* in a size 2 that is *very flexible* (like the existing suture or the [E]thicon sample)" (Ex. 6) (emphasis added). As Mr. Grafton stated, "[i]f we can get this blend correct, we will have a terrific advancement" (Ex. 6). According to Mr. Grafton, Arthrex varied the dissimilar braid materials in type and amount in order to optimize FiberWire's properties:

Q. I would like to know what you mean by in your

letter when you said, "If we can get this blend correct." You asked them for a 25 percent Dyneema/75 percent polyester blend in Size 2 that's very flexible. And then you said, "If we can get this blend correct, we will have a terrific advancement." What did you mean by "If we can get this blend correct"?

A. The optimization of the two materials. If you had the knot strength, loop security, and tensile strength, as well as the tactile feel of the suture all superior to what was on the market, then it would be a superior product.

Q. Wait a second. You said optimization of two materials.

A. (Witness nods head affirmatively).

Q. At this point in time, November 1998, were you trying to vary the amount and type of the Dyneema and polyester in the braid in order to get the best properties?

A. During -- during the -- during that period of time, yes.

Q. So you were balancing off the properties of each material to try to get the optimum properties --

A. Tensile strength.

Q. To get the optimum tensile strength?

A. (Witness nods head affirmatively).

Q. What about knot security?

A. Yes.

Q. Okay. So you were varying the amount and type of the materials to get the optimum knot security, optimum tensile strength?

A. Yes.

Q. Any other properties? Knot tiedown?

A. The slideability of the knot, the tactile feel in the surgeon's hands of the material.

Q. So you were varying type and proportion of the materials to optimize all these properties in the product?

A. Yes.

(Ex. 3 at 68:25-70:13). Further, as explained by Ms. Holloway, FiberWire was braided, so that the individual materials contribute to FiberWire's handleability:

Q. What materials contribute to the handleability of Arthrex's FiberWire sutures?

A. All materials used.

(Ex. 17 at 31:23-25). Thus, in designing FiberWire to have a dissimilar yarn braid, Arthrex specifically designed FiberWire to have the basic and novel characteristics that Dr. Mukherjee attributes to the 446 Patent: (i) a dissimilar yarn braid having the benefits of each yarn; and (ii) improved handleability and pliability without significantly sacrificing physical properties.

Although FiberWire is coated, it still reaps the benefits of this dissimilar yarn braid in terms of handleability/pliability and physical properties. Therefore, the coating does not materially affect the novel and basic characteristics as defined by Dr. Mukherjee.

47. My opinion that FiberWire's coating does not materially affect FiberWire's PET and UHMWPE yarns from being dissimilar, from being braided, and from forming a braid with improved handleability and pliability performance without significantly sacrificing physical properties is further supported by the fact that FiberWire has a very small amount of coating. In fact, it is so small that Pearsalls and Arthrex consider it unmeasureable (Ex. 5 at 119:5-9; Ex. 8 at 94:2-9; Ex. 18 at 48:1-50:16; Ex. 19 at ARM002104). I have personally observed and studied Pearsalls' coating processes for FiberWire during an inspection of Pearsalls' facilities in January 2006. FiberWire is coated by passing a braid of PET and UHMWPE, which has been dyed<sup>3</sup> and scoured, through a bath of NuSil Med 2174 polymer and Xylene solvent at a rate of 20 meters per minute (Ex. 5 at 88:4-9; 82:14-18). Xylene is not a coating. Rather, Xylene is a solvent that dissolves the Med NuSil polymer, so that it can adhere to the FiberWire braid (Ex. 5 at 87:25-88:3; Video of Pearsalls' manufacturing). After passing through the solution, the coated FiberWire is passed through pads, which are compressed together, to wipe away excess coating (Ex. 5 at 97:1-18). Further, FiberWire is passed through a five-stage oven that dries the coating and evaporates the solvent (Ex. 5 at 95:14-17). The process is then repeated. I have measured

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<sup>3</sup> Most FiberWire is dyed blue. But some, such as TigerWire is not. Also, TigerWire has a braid that includes a Nylon marker band in place of one PET yarn.

the amount of coating by weight on FiberWire by determining the linear density (*i.e.*, grams/unit length) of a sample that was not coated, a sample that had been coated once, and sample that had been coated twice (DMI Exhibits 284, 342, and 285, Exs. 20, 21, and 22, respectively). I determined that the linear density of DMI Ex. 284 (uncoated) is 2393 denier, DMI Ex. 342 (coated once) is 2474 denier, and DMI Ex. 285 (coated twice) is 2508 denier using a traditional Mettler balance housed at the Philadelphia University Research Center Materials Evaluation Laboratory. Accordingly, the linear density of DMI Ex. 342 indicates a 3.4% pick-up of coating material from the uncoated DMI Ex. 284. The linear density of Ex. 285 indicates a 1.4% pick-up of additional coating material from DMI Ex. 342. Thus, the total pick-up of Ex. 285 over DMI Ex. 284 is approximately 4.8%. The result of this coating process is that, although FiberWire has a very small amount of coating, FiberWire still has two dissimilar yarns braided together to form a braid with improved handleability and pliability performance without significantly sacrificing physical properties. In other words, the coating did not transform the braided FiberWire materials into another structure or cause it to lose its characteristics that are attributable to the dissimilar yarns being braided. For example, the coating is not applied in a very thick layer and then melted together with the yarns to form a non-braided structure. As Arthrex explains in its instructions for use, FiberWire's coating is just a "lubricant" (Ex. 15).

48. My opinion that FiberWire's coating does not materially affect FiberWire's PET and UHMWPE yarns from being dissimilar, from being braided, and from forming a braid with improved handleability and pliability performance without significantly sacrificing physical properties is supported by both my visual observations of FiberWire, as well as those by CETR. Both my photographs and CETR's show that, even at extreme magnifications, it is difficult to even see coating in certain areas of the suture. In fact, both sets of pictures show that FiberWire

has fibers that retain their morphological attributes, so that they can contribute to the handleability, pliability, and physical properties of FiberWire.

49. I note that Arthrex does not address the issue of whether FiberWire's coating materially affects the fact that it has a dissimilar yarn braid with improved handleability and pliability without significantly sacrificing physical properties. Rather, Arthrex only asserts that FiberWire's coating affects certain individual properties. But that is not the relevant issue even as Arthrex defined the novel and basic characteristics. Rather, the relevant issue as Arthrex framed it was whether FiberWire's coating materially affected FiberWire from being a suture with "two dissimilar yarns braided together to achieve improved handleability and pliability performance without significantly sacrificing its physical properties" (Arthrex Br. at 13). In my opinion, because FiberWire is specifically designed to have precisely these characteristics and its coating is essentially a surface lubricant, FiberWire's coatings effects are not material to the novel and basic characteristics.

**2. Based on the 446 Patent, FiberWire's Coating Does Not Materially Affect the Novel and Basic Characteristic**

50. In order to determine whether an effect on the basic and novel characteristics, as those terms are defined by Arthrex, is "material," I have consulted the 446 Patent to determine what it considers "material" or not "material." In other words, I have considered whether FiberWire's coating is "material" in the context of the invention described in the 446 Patent. Based on the 446 Patent's description of the invention and its description of coatings, FiberWire's coating does not "materially" affect the novel and basic characteristics, as defined by Arthrex.

51. My opinion that FiberWire's coating does not have a "material" effect is based on the 446 Patent's explanation that "coating" is not "material" to the invention. As the 446 Patent explains, the direct intertwining braid of dissimilar materials provides "outstanding properties

attributable to the specific properties of the dissimilar fiber-forming materials which make up the braided yarns" (Ex. 2 at 2:50-52). The 446 Patent further explains that such a braid can be further improved with a coating (*id.* at 6:5-21). Thus, because the 446 Patent specifically contemplates applying coatings of the type used in FiberWire to refine certain braid properties, the 446 Patent does not consider coatings, of the type applied to FiberWire, to have a "material" effect on the basic and novel characteristics of the suture claimed in the 446 Patent.

52. I disagree with Arthrex that FiberWire's coating has a "material" effect because Arthrex basically *excludes* coated sutures from the 446 Patent claims. But this is just contrary to the teachings of the 446 Patent. As the 446 Patent describes, the inventors specifically contemplated preferred embodiments having coatings:

If desired, the surface of the heterogeneous multifilament braid can be coated with a bioabsorbable or nonabsorbable coating to *further* improve the handleability and knot tiedown performance of the braid. For example, the braid can be immersed in a solution of a desired coating polymer in an organic solvent, and then dried to remove the solvent. *Most preferably*, the coating does not cause the fibers or yarns to adhere to one another increasing stiffness. However, if the surface of the heterogeneous braid is engineered to possess a significant fraction of the lubricious yarn system, the conventional coating *may be* eliminated saving expense as well as avoiding the associated braid stiffening.

(*id.* at 6:5-18) (emphasis added). Thus, the inventors specifically *included* coatings within the description of the invention, not *excluded* them. Therefore, because the 446 Patent specifically contemplated coatings, such as that used in FiberWire, it is my opinion that FiberWire's coating cannot be deemed to have a "material" effect on the basic and novel characteristics of the invention.

53. My opinion that FiberWire's "coating" does not have a "material" effect is further supported by the fact that Arthrex and Pearsalls did precisely what the 446 Patent teaches to obtain the basic and novel characteristics that Arthrex attributes to the suture claimed in the 446 Patent. The 446 Patent teaches forming a heterogeneous braid which has a first and a second set

of continuous and discrete yarns (*id.* at 2:40-42). FiberWire's UHMWPE and PET are braided in a heterogeneous braid and are continuous and discrete yarns. The 446 Patent teaches braiding a lubricous yarn with a yarn of different lubricity (*id.* at 4:11-12; 4:33-40). Arthrex and Pearsalls do that; they braid UHMWPE, a lubricous yarn, with PET, a yarn of different lubricity. The 446 Patent teaches braiding dissimilar yarns in direct intertwining contact (*id.* at 2:43-44). Arthrex and Pearsalls braided PET and UHMWPE yarns in direct intertwining contact (Ex. 8 at 107:5-8). The 446 Patent teaches that each yarn has a plurality of filaments (Ex. 2 at 2:45-48). FiberWire's braided UHMWPE and PET yarns each have a plurality of filaments, as shown in Exs. 20, 21, and 22. The 446 Patent teaches braiding yarns to obtain the benefits of each. Arthrex and Pearsalls do that as is shown by its product development (Ex. 3 at 68:25-70:13). The 446 Patent teaches "to tailor" the physical braid properties "by varying the type and proportion of each of the dissimilar fiber forming materials used" (Ex. 2 at 2:58-61). Arthrex did just that by trying different types and amounts of UHMWPE and polyester (Ex. 3 at 68:25-70:13). The 446 Patent teaches coating the braid by immersing it in a solution of a coating polymer and a solvent (Ex. 2 at 6:9-10). Likewise, Pearsalls and Arthrex coat by passing FiberWire through a coating solution (see above). The 446 Patent specifically contemplates that coating can "*further*" improve the handleability of the suture (Ex. 2 at 6:5-18) (emphasis added). The 446 Patent states a preference that coating does not adhere the yarns or fibers to one another thereby increasing stiffness (Ex. 2 at 6:11-13). As shown by the SEM's of the FiberWire, the fibers are not bonded together (Exs. 20, 21 and 22). Thus, because Arthrex and Pearsalls specifically engineered FiberWire to be a nonabsorbable heterogeneous braid, as is precisely described in the 446 Patent, the effects of FiberWire coating can hardly be considered material.

54. I further disagree with Arthrex's focus on FiberWire's coating with reference to defining what is "material" because the 446 Patent is not about "coating" or eliminating "coatings." Rather, the problem addressed by the 446 Patent is how to improve multifilament braided suture properties. For example, the 446 Patent explains that some prior art attempted to improve braided multifilament suture properties at the expense of restricting the movement of adjacent filaments (Ex. 2 at 1:26-29). The 446 Patent then provides some prior art attempts including a certain polyester coating for multifilament sutures (*id.* at 1:32-43), a PTFE coating (*id.* at 1:43-54), a monofilament like surface on a multifilament braid (*id.* at 1:55-2:2), and an elongated core (*id.* at 2:3-13). According to the 446 Patent, these techniques could be improved upon because they did not focus on improving multifilament properties by increasing fiber-to-fiber mobility (*id.* at 2:14-17). Thus, the 446 Patent is not saying that coating was a problem that had to be solved. Rather, the 446 Patent is teaching that certain coatings and other techniques were insufficient *by themselves* to sufficiently improve certain multifilament suture properties.

55. As a solution to the issue of improving multifilament braided suture properties, the 446 Patent teaches braiding dissimilar fiber-forming materials in direct intertwining contact to form a heterogeneous braid, that has properties "attributable to the specific properties of the dissimilar fiber-forming materials" (*id.* at 2:40-53). The 446 Patent also states that certain properties of the dissimilar yarn braid can be "improved" by a coating (*id.* at 6:5-21). Thus, the solution to the issue of improving multifilament braid properties provided by the 446 Patent is to braid dissimilar fiber-forming yarns in direct intertwining contact. Thus, coatings were not material to the issue addressed by the 446 Patent, nor the solution provided. Therefore, the 446 Patent's description of the invention shows that it does not consider coating, as used on FiberWire, to have a "material" effect on the basic and novel characteristics of the claimed suture.

**3. Dr. Burks' Testimony Supports My Opinion that the Effects of FiberWire's Coating Are Not Material**

56. I have reviewed Dr. Burks' testimony and deposition transcript. I understand that he considered the differences between the treated and untreated sutures as "subtle" and "pretty close" (Ex. 23 at 87:7-13; 88:1-3; 96:18-19; 98:18-21). He also stated that he could not "clearly feel a difference" (*id.* at 88:9-10). This supports my opinion that any purported differences are not material.

57. Also, Dr. Burks testified that wearing gloves would make a difference in whether he, as a very experienced surgeon, can even tell the difference between the treated and untreated samples (*id.* at 96:24-97:5; 72:1-73:6). In fact, he testified that he may not have been able to tell a difference if he used just gloves (*id.* at 73:9-14; *see also* 96:24-97:5). He testified that using gloves made a difference in the feel of a suture (*id.* at 72:7-8). I understand from Dr. Burks that he wears gloves when using FiberWire in surgery (*id.* at 51:12-14). Thus, Dr. Burks' testimony regarding the use of gloves supports my opinion that the differences between the treated and untreated sutures are not material.

58. I note that Arthrex criticizes for me for not remembering at my deposition that I had considered certain information in my analyses that Dr. Mukherjee had considered. But after reading Arthrex's criticism, I consulted my Rebuttal Expert Report and it refreshed my memory that I had considered those materials. As I explained in ¶54 of my rebuttal report, I disagree that these documents are relevant to the analysis because they discuss products and coatings that are different than FiberWire. It is my opinion, that the effect of FiberWire's coating on FiberWire cannot be determined with reference to other products with different coatings, different applications of coatings, and different suture constructions. Although I did not recall at my deposition that I had reviewed these documents, I do now recall reviewing them to determine

whether they discussed FiberWire's coating, and they do not. I have provided three reports in this case and reviewed thousands of pages of documents. My deposition was on July 26-27, 2006, just over three months since I finalized my rebuttal report. Although I did not recall that one paragraph from my three reports at my deposition, Arthrex's counsel did not ask me to review that paragraph when asking questions about these documents. If he had, it would have refreshed my memory on the issue.

**V. Under Mitek's Definition of the Novel And Basic Characteristics, FiberWire Infringes Claims 1, 2, 8, 9, and 12 of the 446 Patent**

59. I understand that Arthrex may contend that its FiberWire™ and TigerWire™ products do not infringe claim 1 because they have a coating of NuSil MED-2174. I further understand that the basis of Arthrex's argument is that the coating materially affects the basic and novel characteristics of the claimed invention. As I understand the argument, I disagree with it.

60. I understand that Mitek has asserted that the basic and novel characteristics are a heterogeneous braid of dissimilar non-bioabsorbable yarns of the type claimed, where at least one yarn from the first set is in direct intertwining contact with a yarn from the second set, and the dissimilar yarns have at least some different properties that contribute to the overall properties of the braid. The addition of a coating on FiberWire™ and TigerWire™ does not have any material affect on these basic and novel characteristics. Regardless of the coating, FiberWire™ and TigerWire™ both still have a heterogeneous braid of dissimilar non-bioabsorbable yarns of the type claimed, where at least one yarn from the first set is in direct intertwining contact with a yarn from the second set, and the dissimilar yarns have at least some different properties that contribute to the overall properties of the braid. The coating is non-bioabsorbable and does not materially affect bioabsorbability of the yarns, does not materially affect at least one yarn from the first set being in direct intertwining contact with a yarn from the

second set, and the coating does not materially affect each yarn from contributing to the overall properties of the heterogeneous braid. Furthermore, Arthrex documents describe the coating as a lubricant (Ex. 26 at ARM001976).

61. The '446 Patent specifically contemplates, in the "Detailed Description of the Invention," that the braided sutures of the invention can be coated (Ex. 2 at 6:5-21). The '446 Patent describes the invention as including applying polymer coatings by making a solution of the polymer and a solvent, immersing the suture in the coating and solvent, and drying the suture (*id.* at 6:9-11). Thus, the '446 Patent's description of the invention as contemplating coatings supports my opinion that FiberWire™'s and TigerWire™'s coatings do not materially affect the novel and basic characteristics of the invention because the inventors specifically contemplated coated sutures. Notably, FiberWire™ and TigerWire™ are coated just as the '446 Patent describes; they are immersed in a solution of NuSil MED-2174 and a solvent and dried.<sup>4</sup>

62. Further, I have taken Scanning Electron Micrographs at the Materials Evaluation laboratory at the Philadelphia University Research Center of DMI exhibit 284 (uncoated), DMI exhibit 342 (coated once), and DMI exhibit 285 (coated twice) FiberWire™ suture braids. My Scanning Electron Micrographs are attached at Ex. 21 (DMI Ex. 284), Ex. 22(DMI Ex. 342), Ex. 23 (DMI Ex. 285).

63. It is my expert opinion and observation from the above Micrographs that the coating on the FiberWire™ suture does not substantially permeate the braided structure and does not reside between the braid yarns.

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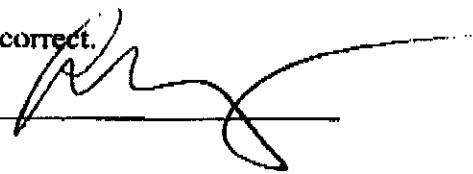
<sup>4</sup> My opinion is further supported because the '446 Patent claims a "suture." I understand that most sutures are coated. Thus, the Patent claims clearly contemplate sutures having coatings, otherwise they would not cover many, if any, sutures.

64. It is my expert opinion and observation that the coating only appears on the surface of the braid.

I declare under penalty of perjury that the foregoing is true and correct.

Date Executed: September 1, 2006

/s/

A handwritten signature in black ink, appearing to read "John Doe", is written over a horizontal line that extends from the end of the "s" in "Date Executed" and ends with a large, stylized "X".

# **BROOKSTEIN DECLARATION**

## **EXHIBIT 1**

David Brookstein, Sc.D.  
Dean and Professor of Engineering  
Philadelphia University  
Philadelphia, PA 19144  
(215) 951-2751

Curriculum Vitae

Education:

- Doctor of Science in the field of Mechanical Engineering, Minor Studies in Management from Sloan School of Management, Massachusetts Institute of Technology, 1976.
- Bachelor of Textile Engineering, Georgia Tech, 1971.
- Harvard University School of Business Summer Program on Research Management, 1990.
- Harvard University Graduate School of Education MLE Summer Program, 1998

Professional Experience:

Philadelphia University

1994 - Present      Dean and Professor of Engineering  
                            School of Textiles and Materials Technology (soon  
                            to be the School of Engineering and Textiles)

Chief academic and financial officer for a school with undergraduate majors in industrial and systems engineering, textile engineering (ABET accredited), textile technology, textile design, fashion design and fashion industry management. Master of Science programs are offered in textile engineering, textile design, textile marketing, global textile marketing, on-line MBA in textile and apparel marketing and fashion-apparel studies. Developed first Philadelphia University program, - Ph.D. in textile engineering and science. Principal Investigator for largest outside funded research grant received by Philadelphia University, \$2.7 million DoD grant for the Laboratory for Engineered Human Protection. Philadelphia University Program Leader for the National Textile Research Center, a \$10 million/annum grant for a consortium of universities that include Auburn University, Georgia Tech, North Carolina State University, Clemson University, UMASS-Dartmouth, Cornell University and University of California-Davis. Led the development of the Philadelphia University Research Center in the Manayunk section of Philadelphia.

Harvard University

2002 - 2003 Visiting Scholar

Harvard University Center for Textile and Apparel  
Research (Division of Engineering and Applied Sciences)

Albany International Research Co. - Mansfield, MA

1992 - 1994 Associate Director

1983 - 1992 Assistant Director

1980 - 1982 Senior Research Associate

Directed all activities of the professional engineering group responsible for contract research, development, and manufacture of advanced composite materials and technical polymeric materials. Accomplishments include the invention and development of the multilayer interlock braiding system for producing three-dimensionally reinforced fibrous preforms for aerospace structures, the development of implantable biomedical devices such as vascular prostheses and orthopedic implants and the development of unique textile-based civil engineering structures. Engineering innovations led to 11 US patents and many other inventions protected by trade secret. Member of the senior management staff of the organization.

Northeastern University - Boston, MA

1981-1983 Adjunct Professor in Mechanical Engineering

Taught undergraduate courses in statics, dynamics, and mechanics of deformable bodies and material science.

Georgia Institute of Technology, College of Engineering

1975 - 1980 Assistant Professor of Textile Engineering

Taught and conducted research in the fields of textile and composites engineering with special emphasis on improving the energy efficiency of manufacturing systems. Obtained substantial funding from US DOE and US DOD. Active participant in College of Engineering co-op undergraduate programs.

**Outside Professional Activities:**

- Advisory Board of the College of Engineering, Georgia Tech.
- Member of the University City Science Center Research Provost Roundtable
- Adjunct Full Professor, North Carolina State University
- President, The Fiber Society (1996)
- Chairman, Textile Engineering Division-American Society of Mechanical Engineers (1994-1996)
- Research Associate - Textile Research Institute/Princeton
- Member of the Manufacturing Technology Operating Group of the ASME
- Peer Reviewer for ASME Fellows

**Memberships:**

- American Society for Engineering Education
- Council of Engineering Deans
- Institute of Industrial Engineers
- ASME - Textile Engineering Division, Chairman, 1980, 1994
- American Conference of Academic Deans
- The Fiber Society - Fiber Society Lecturer, 1986-1987, 1993-1994,
- President (1996)
- SAMPE - Society for Advanced Materials and Process Engineering
- The Textile Institute

**Awards and Honors:**

- ASME - Fellow, 1995
- ASME - Textile Engineering Division, Chairman, 1980, 1994
- The Fiber Society - Fiber Society Lecturer, 1986-1987, 1993-1994, President, 1996
- The Textile Institute (United Kingdom) - Fellow, 1992
- Georgia Tech Academy of Distinguished Engineering Alumni, 1999
- Techtextil Innovation Prize, 1993 (Germany)
- ASTM Harold Dewitt Smith Award, 1998

**Publications:**

"Deductions about the False-Twist Process from Observations of the Variation of Torque on Detwisting at Heat Set Yarn," with Backer, S., and Thwaites, J.J., Journal of the Textile Institute, 67, p. 183-186, 1976.

"Transient Threadline Behavior in False-Twist Texturing," with Thwaites, J.J., and Backer, S., Journal of the Textile Institute, 67, 1976.

"Mechanics of Texturing Thermoplastic Yarns: Part III. Experimental Observations of Torsional Behavior of the Texturing Threadline for Pre-Drawn PET Yarns," with Backer, S., Textile Research Journal, 46, pp. 802-908, 1976.

"Mechanics of Texturing Thermoplastic Yarns: Part V. Steady State Mechanics of Drawing Texturing," Textile Research Journal, 47, p. 256-266, 1977

"Material-Process Interactions During False-Twist Texturing," with Backer, S., Journal of Applied Polymer Science: Applied Polymer Symposium, 31, p. 63-82, 1977.

"Mechanics of Texturing Thermoplastic Yarns: Part VI. Transient Mechanics of Draw Texturing," with Backer, S., Textile Research Journal, 48, p. 198-218, 1978.

"On the Mechanics of Draw Texturing," Journal of Applied Polymer Science: Applied Polymer Symposium, 33, p. 197-202, 1978

"Energy Consumption and Conservation: Textile Drying," ACS Symposium Series, 107/17, 1979

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"Energy Conservation in the Textile Industry," ERDA - Phase I Report, DOE, April, 1977, Quarterly Reports, 1976 to 1977, Final Report.

"Processing of Pitch-Based Staple Carbon Fiber," Union Carbide Corporation, November 1977, Final Report.

"Low Thermal Conductivity of PAN-Based Carbon Fiber, Hercules, Inc., Monthly Reports and Final Report

"Development and Demonstration of Energy-Conserving Drying Modifications to Textile Processes," U.S. DOE Monthly Reports.

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3. U.S. Patent 4,602,892 "Sucker Rod," A braided composite rod and coupling for pumping oil.
4. U.S. Patent 4,841,613 "Pressure Developer or Press Roll Containing Composite Material," A composite press roll with variation of radial stiffness.
5. U.S. Patent 4,909,127 "Braiders," A braider with non-circular braider tracks and a unique package carrier for use with braider.
6. U.S. Patent 5,004,474 "Prosthetic Anterior Cruciate Ligament Design," An artificial ligament device having a tubular woven ligament and being adapted for joining the ends of two bones.
7. U.S. Patent 5,357,839 "Solid Braid Structure" A 3-D system for producing braids.
8. U.S. Patent 5,358,758 "Structural Member" A fiber reinforced structural member produced from a complex woven fabric.
9. U.S. Patent 5,411,463 "Composite Roll and Method of Making" A fiber reinforced roll for papermaking.
10. U.S. Patent 5,501,133 "Apparatus for Making a Braid Structure" A novel manufacturing system for producing 3-D multilayer interlock braided textile and fiber reinforced composite structures.
11. U.S. Patent 5,697,969 "Vascular Prosthesis and Method for Implanting" A fibrous synthetic vascular graft with a combination of resorbable and non-resorbable layers.

**Non-patentable trade secret inventions developed at Albany International Research Co.**

1. Fiber-reinforced composite rocket igniter for Small ICBM and Pegasus Air-Launched Vehicle
2. Specialty vascular grafts and bio-absorbable orthopedic implants
3. Flexible air-beam for military structures
4. New method for drying paper during the papermaking process
5. Complex, reduced delamination rocket motor exit cones

# **BROOKSTEIN DECLARATION**

## **EXHIBIT 2**



US005314446A

## United States Patent [19]

Hunter et al.

[11] Patent Number: 5,314,446  
 [45] Date of Patent: May 24, 1994

## [54] STERILIZED HETEROGENEOUS BRAIDS

[75] Inventors: Alastair W. Hunter, Bridgewater; Arthur Taylor, Jr., Plainfield, both of N.J.; Mark Steckel, Maineville, Ohio

[73] Assignee: Ethicon, Inc., Somerville, N.J.

[21] Appl. No.: 838,511

[22] Filed: Feb. 19, 1992

[31] Int. Cl.: D04C 1/00

[52] U.S. Cl.: 606/231; 606/228; 87/7; 87/9; 428/370

[58] Field of Search: 606/228, 230, 231; 87/7, 8, 9; 428/225

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3,942,532	3/1976	Hunter et al.	128/335.5
4,043,344	8/1977	Landi et al.	128/335.5
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4,052,988	10/1977	Doddi et al.	128/335.5
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4,470,941	9/1984	Kurtz	264/136

4,624,256	11/1986	Messier et al.	128/335.5
4,946,467	8/1990	Ohi et al.	606/228
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Primary Examiner—George F. Lesmes

Assistant Examiner—Chris Raimund

Attorney, Agent, or Firm—Hal Brent Woodrow

## [57] ABSTRACT

Heterogeneous braided multifilament of first and second set of yarns mechanically blended by braiding, in which first and second set of yarns are composed of different fiber-forming materials.

Heterogeneous braids are useful for preparation of surgical sutures and ligatures.

12 Claims, 3 Drawing Sheets

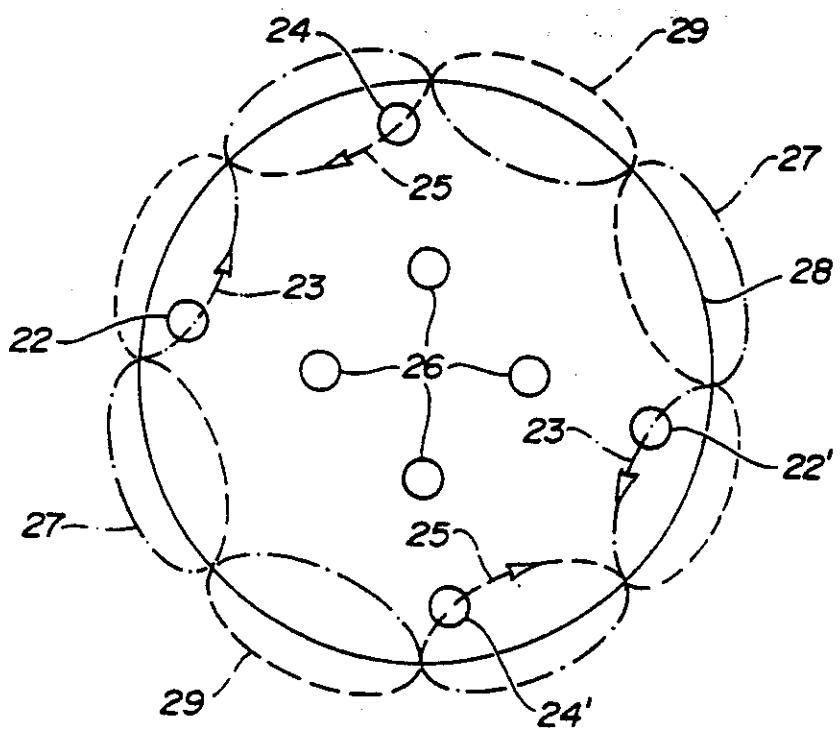
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FIG-1



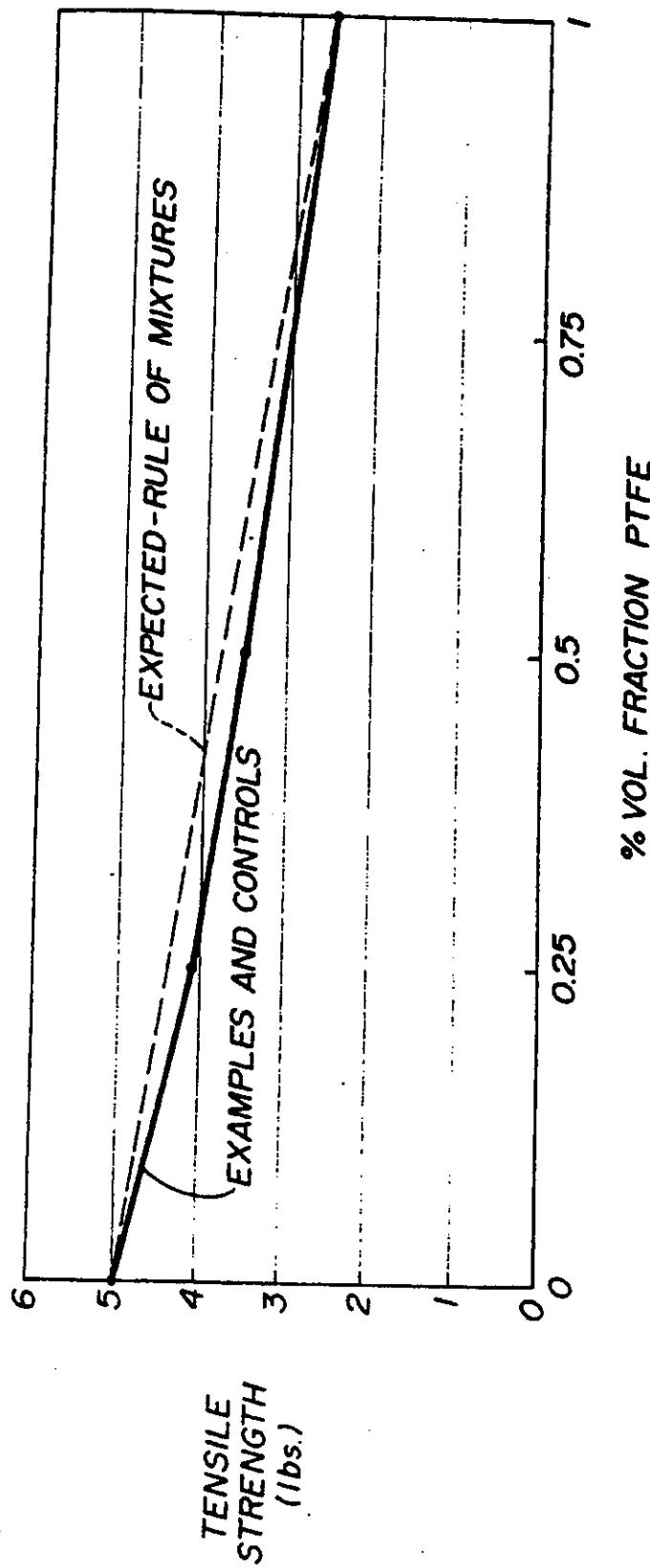
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FIG-2



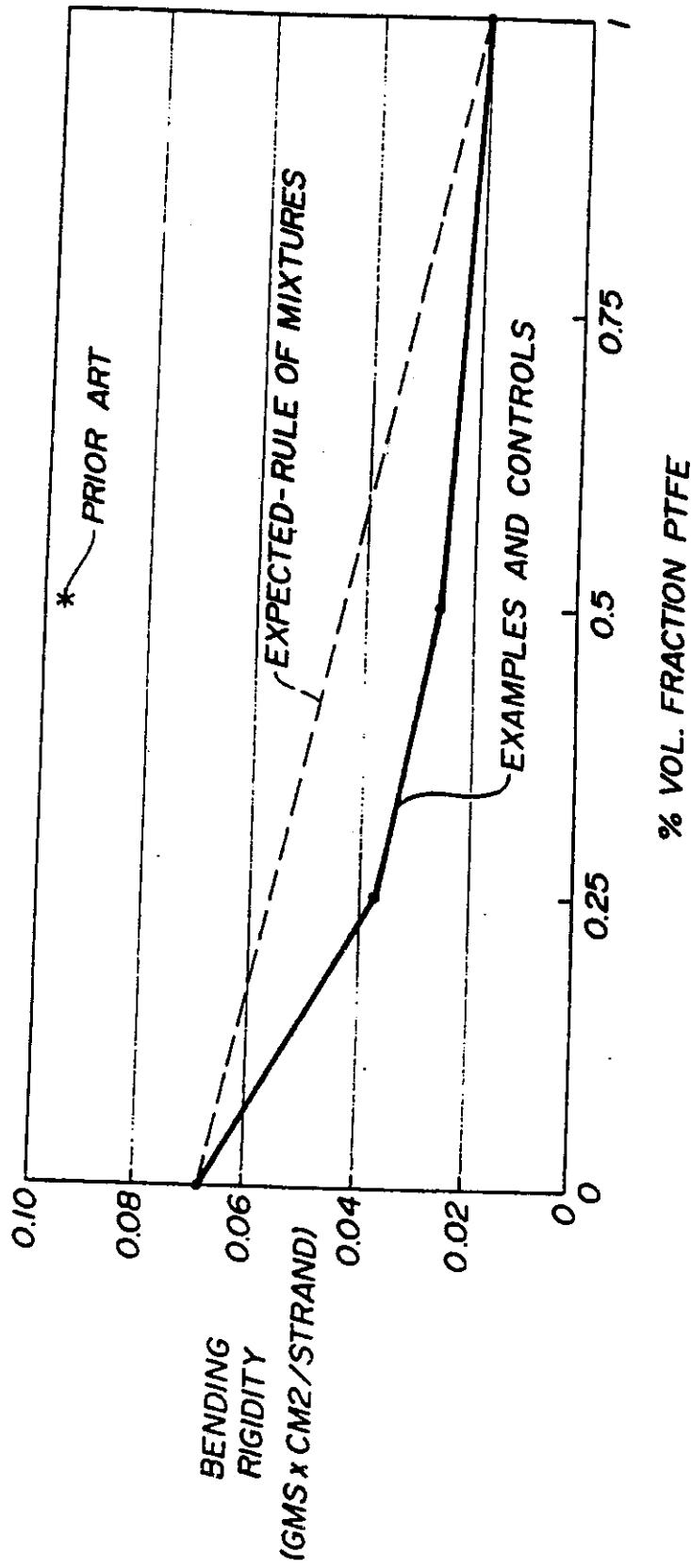
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FIG-3



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## STERILIZED HETEROGENEOUS BRAIDS

## BACKGROUND OF THE INVENTION

This invention relates to braided multifilaments, and especially to sterilized, braided multifilaments suitably adapted for use as surgical sutures or ligatures.

Braided multifilaments often offer a combination of enhanced pliability, knot security and tensile strength when compared to their monofilament counterparts. The enhanced pliability of a braided multifilament is a direct consequence of the lower resistance to bending of a bundle of very fine filaments relative to one large diameter monofilament. However, for this enhancement to be realized, the individual multifilaments must be able to bend unencumbered or unrestricted by their neighboring filaments. Any mechanism which reduces this individual fiber mobility, such as simple fiber-fiber friction, a coating which penetrates into the braid interstices, or a melted polymer matrix which adheres fibers together, will adversely affect braid pliability. In the extreme case where the multifilaments are entirely bonded together, the pliability or bending resistance closely approximates that of a monofilament.

Unfortunately, the prior art abounds with attempts to improve specific properties of multifilament braids at the expense of restricting the movement of adjacent filaments which make up the braid. For example, multifilament sutures almost universally possess a surface coating to improve handling properties.

U.S. Pat. No. 3,942,532 discloses a polyester coating for multifilament sutures. The preferred polyester coating is polybutylate, which is the condensation product of 1,4-butanediol and adipic acid. U.S. Pat. No. 4,624,256 discloses a suture coating copolymer of at least 90 percent  $\epsilon$ -caprolactone and a biodegradable monomer, and optionally a lubricating agent. Examples of monomers for biodegradable polymers disclosed include glycolic acid and glycolide, as well as other well known monomers typically used to prepare bioabsorbable coatings for multifilament sutures.

An alternative to the use of the commonly accepted coating compositions for multifilament sutures to improve handling properties is disclosed in U.S. Pat. 3,527,650. This patent discloses a coating composition of polytetrafluoroethylene (PTFE) particles in an acrylic latex. Although the PTFE particles act as an excellent lubricant to decrease the surface roughness of multifilament sutures, the particles have a tendency to flake off during use. Also, this particular coating is a thermoset which requires a curing step for proper application.

More recently, a dramatic attempt has been made to create a monofilament-like surface for a multifilament suture. U.S. Pat. No. 4,470,941 discloses the preparation of "composite" sutures derived from different synthetic polymers. The composite suture is composed of a core of low melting fibers around which are braided high melting fibers. Because of the lack of cohesiveness of the dissimilar fibers, the low melting fibers in the core are melted and redistributed throughout the matrix of the braided, high melting fibers. Although these composite sutures represent an attempt to combine the best properties of different synthetic fibers, it unfortunately fails in this respect due to increased stiffness (as evidenced by FIG. 3 which is described in detail below),

apparently due to the reduction of fiber mobility resulting from the fusing of the fibers together.

Another attempt to enhance the properties of multifilament sutures can be found in WO 86/00020. This application discloses coating an elongated core of a synthetic polymer having a knot tenacity of at least 7 grams/denier with a film-forming surgical material. The film-forming surgical material can be absorbable or nonabsorbable, and can be coated on the elongated core by solution casting, melt coating or extrusion coating. Such coated multifilament sutures suffer from the same deficiencies which plague conventionally coated multifilament sutures.

All of the attempts described in the prior art to improve braid properties have overlooked the importance of fiber-fiber friction and its impact on fiber mobility and braid pliability. The properties of concern here include the fiber-fiber frictional coefficients (which frequently relate to the polymer's surface energy), the fiber cross-sectional shape and diameter, and the braid structure which influences the transverse forces across the braid. If fibers composed of highly lubricous polymers are used in the traditional manner, then a highly pliable braid can be prepared. However, in most cases, these braids will be relatively weak and unusable. Hence, a tradeoff between braid strength and pliability exists in the design of conventional braided multifilament sutures.

In view of the deficiencies of the prior art, it would be desirable to prepare multifilament sutures exhibiting improved pliability and handling properties. More specifically, it would be most desirable to prepare braided multifilaments composed of dissimilar fiber-forming materials in which the fiber-forming materials contribute significantly to enhanced pliability for the braided multifilament without appreciably sacrificing its physical properties.

## SUMMARY OF THE INVENTION

The invention is a heterogeneous braid comprising a first and second set of continuous and discrete yarns in a sterilized, braided construction. At least one yarn from the first set is in direct intertwining contact with a yarn from the second set.

Each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material, and each yarn from the second set is composed of a plurality of filaments of a second fiber-forming material.

Surprisingly, the heterogeneous braids may exhibit a combination of outstanding properties attributable to the specific properties of the dissimilar fiber-forming materials which make up the braided yarns. The dissimilar fiber forming materials do not require melt bonding or any other special processing techniques to prepare the heterogeneous braids of this invention. Instead, the integrity of the braid and therefore its properties is due entirely to the mechanical interlocking or weaving of the individual yarns. In fact, it is possible to tailor the physical and biological properties of the braid by varying the type and proportion of each of the dissimilar fiber forming materials used, as well as adjusting the specific configuration of the braid. For example, in preferred embodiments, the heterogeneous braid will exhibit improved pliability and handling properties relative to that of conventional homogeneous fiber braids, without sacrificing physical strength or knot security.

The sterilized, heterogeneous braids of this invention are useful as surgical sutures or ligatures, as well as for

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the preparation of any other medical device which would benefit from its outstanding physical or biological properties.

#### BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 illustrates a carrier layout for the preparation of a heterogeneous braid within the scope of this invention;

FIG. 2 is a plot representing the relationship between the tensile strength of heterogeneous and homogeneous braids of polyethylene terephthalate (PET) and PTFE yarns, and the volume fraction of PTFE yarns in the braids; and

FIG. 3 is a plot representing a relationship between the initial bending rigidity of heterogeneous and homogeneous braids of PET and PTFE yarns, and the volume fraction of PTFE yarns in the braids.

#### DETAILED DESCRIPTION OF THE INVENTION

For purposes of describing this invention, a "heterogeneous" braid is a configuration composed of at least two sets of dissimilar yarns mechanically blended by intertwining the dissimilar yarns in a braided construction. The yarns are continuous and discrete, so therefore each yarn extends substantially along the entire length of the braid and maintains its individual integrity during braid preparation, processing and use.

The heterogeneous braids of this invention can be conventionally braided in a tubular sheath around a core of longitudinally extending yarns, although such a core may be excluded, if desired. Braided sheath sutures with central cores are shown in U.S. Pat. Nos. 3,187,752; 4,043,344; and 4,047,533, for example. A core may be advantageous because it can provide resistance to flattening, as well as increased strength. Alternatively, the braids of this invention can be woven in a spiral or spiroid braid, or a lattice braid, as described in U.S. Pat. Nos. 4,959,069 and 5,059,213.

The dissimilar yarns of the first and second set of 40 yarns are braided in such a manner that at least one yarn from the first set is directly intertwined with, or entangled about, a yarn from the second set. Direct mechanical blending of individual, dissimilar yarns therefore occurs from the interweaving and interlocking of these dissimilar yarns, enhancing yarn compatibility and the overall physical and biological properties of the heterogeneous braid. Preferably, every yarn from the first set is in direct intertwining contact with a yarn of the second set to achieve the maximum degree of mechanical blending of the dissimilar yarns.

The first and second fiber-forming materials which make up the filaments of the first and second set of yarns, respectively, can be any materials capable of being spun into continuous filaments. Advantageously, the fiber-forming materials are nonmetallic.

The preferred fiber-forming materials are synthetic fiber-forming polymers which are melt or solution spun through a spinneret to prepare continuous filaments. The filaments so prepared are advantageously stretched 60 to provide molecular orientation and annealed to enhance dimensional stability and/or biological performance. The fiber-forming polymers can be bioabsorbable or nonabsorbable, depending on the particular application desired. Examples of monomers from which 65 bioabsorbable polymers are derived include, but are not limited to, some hydroxyacids and lactones, e.g. glycolic acid, lactic acid, glycolide, lactide, p-dioxanone,

ε-caprolactone and trimethylene carbonate, as well as copolymers and polymer blends derived from these monomers and others. Interestingly, numerous bioabsorbable heterogeneous braids exhibiting varying useful biological properties, such as breaking strength retention in vivo and the absorption profiles in vivo, can be prepared for specific applications by using different combinations of bioabsorbable polymers.

Preferably, the continuous filaments which make up 10 the first and second set of yarns are derived from nonabsorbable polymers. In a preferred embodiment, the first set of yarns acts as lubricating yarns to improve the overall pliability, or compliance, and surface lubricity of the heterogeneous braid. Preferably, the fiber-forming material of the first set exhibits a surface energy (which frequently relates to surface lubricity) less than about 38 dyne/cm, as measured by contact angle of liquids on polymer surfaces, as described by Kissa, E., "Handbook of Fiber Science and Technology," Vol. II, Part B, Marcel Dekker, 1984. Such fiber forming polymers include perfluorinated polymers, e.g. PTFE and fluorinated ethylene/propylene copolymers (FEP) and perfluoroalkoxy (PFA) polymers, as well as non-perfluorinated polymers such as polyvinylidene fluoride (PVDF), polyethylene/tetrafluoroethylene copolymers (PETFE), the polychlorofluoroethylene polymers, polypropylene (PP) and polyethylene (PE). More preferably, the first fiber-forming material exhibits a surface energy less than about 30 dyne/cm. The preferred polymers for the first set are PTFE, PETFE, FEP, PE and PP, and the most preferred fiber forming polymer is PTFE.

In a more preferred embodiment, the lubricating 35 yarns of the first set are mechanically blended with yarns of the second set which act to provide improved strength to the heterogeneous braid. Preferably, the second set of yarns exhibits a yarn tenacity greater than 3.0 grams/denier, more preferably greater than 5.0 grams denier. The preferred yarns are PET, nylon and aramid, and the most preferred yarns are PET.

In the most preferred embodiment, the heterogeneous braid is composed of a first set of PTFE yarns mechanically blended with a second set of PET yarns in a braided configuration. Advantageously, the braided 45 sheath encloses a core of longitudinally extending PET yarns to further improve the overall strength and resistance to flattening of the heterogeneous braid. In this embodiment, the volume fraction of lubricating yarns in the braided sheath and core desirably ranges from about 20 to about 80 percent. A volume fraction of lubricating 50 yarns below about 20 percent will not typically improve the pliability of the braid, and a volume fraction above about 80 percent may adversely affect the overall strength of the braid. The filament fineness for such a heterogeneous braid is preferably less than 10 denier per filament, preferably from about 0.5 to about 5 denier per filament. A more coarse filament may result in a stiffer braid. The preferred individual yarn denier is between 10 and 100 denier.

The heterogeneous braids of this invention can be prepared using conventional braiding technology and equipment commonly used in the textile industry, and in the medical industry for preparing multifilament sutures. For example, the first and second set of yarns can be interwoven as indicated by the plan view of the 60 yarn carrier layout of FIG. 1 for the preparation of a braided multifilament. The individual yarns of the braided sheath feed from spools mounted on carriers 22, 22' and

24, 24'. The carriers move around the closed circular loop 28, moving alternately inside and outside the loop 28 to form the braiding pattern. One or more carriers are continually following a serpentine path in a first direction around the loop, while the remaining carriers are following a serpentine path in the other direction.

In the illustrated embodiment, carriers 22, 22' are travelling around serpentine path 27 in a clockwise direction as indicated by directional arrows 23, and carriers 24, 24' are travelling around serpentine path 29 in a counterclockwise direction as indicated by arrows 25. The moving carriers dispense yarns which intertwine to form the braid. The yarns from all the carriers in a constructed embodiment of FIG. 1 are dispensed upward with respect to the plane of the drawing, and the braid is taken up on a reel located above the plane of the drawing.

In one embodiment, moving carriers 22, 24 dispense yarns of the first set and moving carriers 22', 24' dispense yarns of the second set to form the heterogeneous braid. In a more preferred embodiment, moving carriers 22, 22' dispense yarns of the first set and moving carriers 24, 24' dispense yarns of the second set. This carrier layout provides a braid in which each yarn of the first set is directly intertwined with a yarn from the second set.

Advantageously, as illustrated in FIG. 1, disposed within the center of the loop 28 are carriers 26 which dispense the core yarns of the braid. In the most preferred embodiment of this invention, moving carriers 22, 22' dispense PTFE yarns, moving carriers 24, 24' dispense PET yarns, and core carriers 26 dispense PET yarns.

Numerous additional embodiments are contemplated within the scope of the invention using conventional braiding technology and equipment. For example, the carrier layout can be modified to prepare a braid configuration using from 3 to 28 sheath carriers, with or without any number of core yarns. Dissimilar yarns from the first and second set of yarns can be plied together using conventional techniques before braiding, and in this embodiment, the carriers can dispense identical bobbins of plied yarns composed of individual yarns from the first and second sets. This embodiment not only offers the advantage of inter-yarn mechanical blending, but also the intimate mixing associated with intra-yarn blending.

Similar to the preparation of conventional homogeneous braids, the yarns from which the heterogeneous braids are prepared are preferably nontextured. The yarn tension during braiding is advantageously adjusted so that the yarn elongation for each set of yarns is about equal. The equilibration of yarn elongation may prevent irregularities, for example, "core popping", which is the tendency of core yarns to break through the braided sheath as the braid is bent. The number of picks per inch in the finished braid can be adjusted to balance the tensile strength of the braid with braid quality, e.g. the tendency for core popping and overall braid smoothness.

After the heterogeneous braid is prepared, it is desirably scoured to remove machine oils and lubricants, and any foreign particles. The scoured braid is preferably stretched at a temperature between the glass transition temperature and melting temperature of the lower melting set of yarns. Therefore, the stretching temperature is such that none of the yarns is actually melted. The stretching operation densifies the braid and improves

braid smoothness. Afterwards, the braid may be annealed while under restraint to improve dimensional stability, and in the case of absorbable braids, to improve the breaking strength retention in vivo.

If desired, the surface of the heterogeneous multifilament braid can be coated with a bioabsorbable or nonabsorbable coating to further improve the handleability and knot tiedown performance of the braid. For example, the braid can be immersed in a solution of a desired coating polymer in an organic solvent, and then dried to remove the solvent. Most preferably, the coating does not cause the fibers or yarns to adhere to one another increasing stiffness. However, if the surface of the heterogeneous braid is engineered to possess a significant fraction of the lubricious yarn system, the conventional coating may be eliminated saving expense as well as avoiding the associated braid stiffening.

If the surface of the braid is coated, than the coating composition may desirably contain bioactive materials such as antibiotics and growth factors.

The post-treated heterogeneous braid is sterilized so it can be used for a host of medical applications, especially for use as a surgical suture, preferably attached to a needle. The braid can be sterilized using any of the conventional techniques well known in the art. For example, sterilization can be effected by exposing the braid to gamma radiation from a cobalt 60 source. Alternatively, the braid can be sterilized by exposure to ethylene oxide.

In the following examples, the tensile properties and knot security are each determined using an Instron Tensile Tester. The tensile properties, i.e. the straight and knot tensile strength and the percent elongation, are determined generally according to the procedures described in U.S. Pat. No. 4,838,267. The knot security, which provides an indication as to the number of throws required to secure a knot so that it fails to slip before cleanly breaking, is measured by first tying a conventional square knot around a mandrel, pulling the knot apart on the Instron Tester to observe whether slipping occurs, and if so, then tying knots with additional throws until 20 out of 20 knots break cleanly without slipping. The bending rigidity, which is the inverse of pliability, is determined using a Kawabata Pure Bending Tester, as discussed in "The Effects of Structure on the Geometric and Bending Properties of Small Diameter Braids", Drexel University Master Thesis, 1991, by Mr. E. Ritter.

The examples are illustrative only, and are not intended to limit the scope of the claimed invention. The types of yarns used to prepare the heterogeneous braid and the yarn geometry can be varied to prepare heterogeneous braids within the scope of the claimed invention which exhibit a combination of outstanding physical or biological properties.

## EXAMPLES

Examples I and II describe heterogeneous braids of PTFE and PET yarns. In order to evaluate the relative performance of these braids, two controls are included which represent 100% PET and 100% PTFE braids, respectively. To the extent possible, the yarn materials and processing conditions are identical for the controls and heterogeneous braid examples. In addition, for comparison purposes, a braid is fabricated with identical materials but processed per the prior art U.S. Pat. No. 4,470,941.

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## CONTROL I

**FIBER MATERIALS:** An 8×0 PET braid is fabricated, i.e. 8 sheath yarns and 0 core yarns. All yarns are Dupont Dacron PET, 70 denier, 48 filament, type 52 yarn.

**PROCESSING:** The yarns are wound on braider

**PROCESSING:** Identical to EXAMPLE I, except that the hot stretch temperature is at 300° C. and for a longer residence time to facilitate melting of the PET fibers.

**5** The properties of CONTROLS I and II, and EXAMPLES I and II, and the PRIOR ART I are summarized in the following Table:

	USP DIAMETER (mils)	TENSILE STRENGTH (lbs)	KNOT STRENGTH (lbs)	BENDING RIGIDITY (gm x cm <sup>2</sup> )	KNOT STABILITY (# of throws)
CONTROL I	10.68	4.98	3.14	0.0680	4
CONTROL II	9.11	2.58	2.04	0.0196	7
EXAMPLE I	9.71	3.55	2.41	0.0257	5
EXAMPLE II	10.35	4.10	2.67	0.0371	5
PRIOR ART I	8.81			0.0966	

20 bobbins per conventional methods, and the bobbins loaded on each carrier of a N.E. Butt 8 carrier braider. Machine settings include: 32 pick gear, 0.009" wire tension springs, and 183 rpm. The braid is aqueous scoured, and hot stretched at 30% draw ratio at 225° C.

## CONTROL II

**FIBER MATERIALS:** An 8×0 PTFE braid is fabricated. All yarns are Dupont Teflon, 110 denier, 12 filament.

**PROCESSING:** The yarns are wound on braider bobbins per conventional methods, and the bobbins loaded on each carrier of a N.E. Butt 8 carrier braider. Machine settings include: 36 pick gear, no tension springs, and 183 rpm. The braid is scoured and hot stretched per the conditions described in CONTROL I.

## EXAMPLE I

**FIBER MATERIALS:** An 8×0 heterogeneous braid is fabricated, consisting of four PET 70 denier yarns and four PTFE 110 denier yarns. The yarns are identical to that employed in CONTROL I and II. On a volume basis, the braid is 50.3% PET, and 49.7% PTFE.

**PROCESSING:** Four bobbins of PET yarn and four bobbins of PTFE yarn were wound by conventional means. The PET bobbins were loaded on the clockwise moving carriers of the N.E. Butt 8 carrier braider, and the PTFE yarn bobbins on the counter-clockwise moving carriers. Machine settings include: 32 pick gear, 0.009" tension springs on PET carriers, no springs on PTFE carriers, and 183 rpm. The braid is scoured and hot stretched per the conditions described in CONTROL I.

## EXAMPLE II

**FIBER MATERIALS:** Identical to EXAMPLE I, except that 6 PET yarns and 2 PTFE yarns were used. On a volume basis, the braid is 75.5% PET, and 24.5% PTFE.

**PROCESSING:** Identical to EXAMPLE I, except that 2 PET bobbins replace 2 PTFE bobbins. All other braider machine settings, scour and hot-stretch conditions are identical to CONTROL I and II and EXAMPLE I.

## PRIOR ART I

**FIBER MATERIALS:** Identical to EXAMPLE I. On a volume basis, the braid is 50.3% PET, and 49.7% PTFE.

As may be expected, the tensile strengths of the heterogeneous braid examples reflect the relative contributions of the individual components. This behavior is said to follow the "rule of mixtures", i.e. the composite property is a weighted average of the component properties. In equation form,

$$P_c = (V_a) (P_a) + (V_b) (P_b)$$

where  $P_c$  is a composite property (such as tensile strength or modulus),  $P_a$  and  $P_b$  are the properties of the components a and b, and  $V_a$  and  $V_b$  are the volume fractions of components a and b. This behavior is clearly observed in FIG. 2, which shows a plot of tensile strength versus volume fraction of PTFE yarns for the Examples and Controls, in relation to the expected plot according to the rule of mixtures.

Surprisingly, the bending rigidity of the heterogeneous braids in EXAMPLES I and II do not follow the rule of mixtures, and show an enhanced bending rigidity relative to the weighted average of its components. This is shown in FIG. 3 as a plot of bending rigidity versus %PTFE in the braids. Bending rigidity is the inverse of pliability, and is obtained by measuring the slope of the bending moment-radius of curvature plot of a suture strand in pure bending. Hence lower bending rigidity relates to a more pliable suture, which is a highly desirable property. The mechanism of this enhanced pliability is believed to be internal lubrication of the braid by the "solid lubricant" behavior of the low surface energy PTFE.

U.S. Pat. No. 4,470,941 discloses the preparation of a "composite" suture with a monofilament-like surface made from multifilament yarns. The composite suture is composed of two different synthetic polymer fibers, which is thermally processed to melt one of the fibers to form a continuous matrix. This process was utilized to produce the PRIOR ART I example, the data of which is shown in Table I and FIG. 3. It is observed that the melting of the PET fibers significantly increases the braid bending rigidity due to the bonding of the "non-melted" fibers together, hence resulting in a less pliable braid of diminished utility.

What is claimed is:

1. A surgical suture consisting essentially of a heterogeneous braid composed of a first and second set of continuous and discrete yarns in a sterilized, braided construction wherein at least one yarn from the first set is in direct intertwining contact with a yarn from the second set; and

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- a) each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material selected from the group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and PE; and
- b) each yarn from the second set is composed of a plurality of filaments of a second fiber-forming material selected from the group consisting of PET, nylon and aramid; and
- c) optionally a core.

2. The surgical suture of claim 1 wherein the suture is attached to a needle.

3. The surgical suture of claim 1 wherein the first fiber-forming material exhibits a surface energy less than about 38 dynes/cm.

4. The surgical suture of claim 3 wherein the first fiber-forming material exhibits a surface energy less than about 30 dynes/cm.

5. The surgical suture of claim 4 wherein the first set of yarns is PTFE.

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- 6. The surgical suture of claim 5 wherein the second set of yarns exhibits a yarn tenacity greater than 3.0 grams/denier.
- 7. The surgical suture of claim 6 wherein the second set of yarns exhibits a yarn tenacity greater than 5.0 grams/denier.
- 8. The surgical suture of claim 1 wherein the second set of yarns is PET.
- 9. The surgical suture of claim 8 wherein the volume fraction of the first set of yarns in the braided sheath and core ranges from about 20 to about 80 percent.
- 10. The surgical suture of claim 9 wherein the fiber fineness of the yarns of the first and second sets is less than 10 denier per filament.
- 11. The surgical suture of claim 1 wherein at least one yarn from the first set of yarns is plied together to a yarn from the second set of yarns.
- 12. The surgical suture of claim 8 wherein the suture is attached to a needle.

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# **BROOKSTEIN DECLARATION**

## **EXHIBIT 3**

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2  
3 IN THE UNITED STATES DISTRICT COURT  
4 FOR THE DISTRICT OF MASSACHUSETTS  
5

6 DePuy Mitek, Inc., a  
7 Massachusetts Corporation,  
8

9 Plaintiff,  
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11 vs.  
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13 Arthrex, Inc., a Delaware  
14 Corporation,  
15

16 Defendant.  
17

18 CIVIL ACTION  
19 NO. 04-12457 PBS  
20

21 DEPOSITION OF:

22 DONALD GRAFTON  
23

24 DATE:

25 March 14, 2006  
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LOCATION:

The Ritz Carlton Golf Resort  
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REPORTER:

Deborah A. Krotz, RPR, CRR  
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VIDEOGRAPHER:

Gene Howell, CLVS  
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1 Q. And you don't recall whether or not the polyester  
2 suture from Arthrex had a core?  
3 A. You said from Arthrex. You're talking about  
4 Pearsalls now?  
5 Q. I'm sorry. The 100 percent polyester suture from  
6 Pearsalls, did it have a core?  
7 A. Don't know.  
8 Q. Don't know? And the polyester that was braided  
9 in the polyester suture from Pearsalls, do you know what  
10 type of polyester that was?  
11 A. No.  
12 Q. When's the first time that you went over to  
13 England to visit Pearsalls?  
14 A. Don't remember.  
15 Q. How many times have you been over to England to  
16 visit Pearsalls?  
17 A. Three to five.  
18 Q. When you were involved in the process of  
19 selecting this polyester suture from Pearsalls, did you go  
20 over and visit Pearsalls?  
21 A. No.  
22 Q. No? At some point, Arthrex -- Let me back up.  
23 What was the next suture that you can remember  
24 Arthrex selling after the polyester?  
25 A. Jenzyme Tevdek.

22 1 Q. Knot tiedown? Is that one of the considerations?  
2 A. Knot -- knot strength.  
3 Q. Was knot tiedown one of the considerations  
4 that --  
5 A. Well, obviously, if you are going to tie a knot,  
6 I mean, it's going to be tied down to something. Yes.  
7 The makeup of the suture anchor, so, yes.  
8 Q. So the answer is yes?  
9 A. Yes.  
10 Q. Okay. When you were selecting the Pearsalls  
11 suture, was knot strength a consideration?  
12 A. Of course.  
13 Q. And when you were selecting the Pearsalls suture,  
14 was tensile strength a consideration?  
15 A. Yes.  
16 Q. When you were selecting the Pearsalls suture, was  
17 knot tiedown a consideration?  
18 A. Knot tiedown, knot strength are -- in my thinking  
19 are similar or the same thing.  
20 Q. Same thing?  
21 A. (Witness nods head affirmatively).  
22 Q. What do you mean -- In your thinking, when you  
23 say knot strength, what do you mean?  
24 A. Surgeon's application is to tie a knot. That is  
25 affixing it to -- in approximation to tissue to bone.

23 1 Q. Were you involved in the selection of the Tevdek  
2 suture?  
3 A. What do you mean involved? Primary  
4 identification or selection or did I know the company? Or  
5 you are going to have to -- When you say involved, sir, I  
6 need to know exactly what you're talking about.  
7 Q. Okay. Were you involved in the selection of this  
8 Tevdek suture from Jenzyme?  
9 MR. SOFFEN: Objection; vague. He just said he  
10 doesn't have --  
11 A. I'm not sure -- Again, when you say involved, I'm  
12 involved in this, but I'm not asking the questions. So  
13 you need to -- when you say involved, what does involved  
14 mean exactly? I -- I was the engineer that was  
15 responsible for saying yes, this is a product that meets  
16 engineering specifications.  
17 Q. Okay. Did you recommend that Arthrex sell the  
18 Tevdek sutures?  
19 A. From an engineering standpoint, the material met  
20 the specification or engineering requirements to be used  
21 with a suture anchor.  
22 Q. And what were the engineering requirements that  
23 you reviewed Tevdek suture for?  
24 A. Knot strength, tensile strength, color,  
25 biocompatibility. You know. It's -- on and on.

25 1 That is knot tiedown. And there's a knot placed in the  
2 suture, so -- so tying a knot and knot tiedown are the  
3 same things as far as I'm concerned.  
4 Q. Okay. You just said tying a knot and knot  
5 tiedown is the same thing. My question was slightly  
6 different. Knot strength versus -- What is your  
7 understanding of knot strength?  
8 A. It's the mechanical tensile of the suture's  
9 ability to -- to, after tying a knot, before breakage.  
10 Q. Did you generally consider knot strength to be  
11 determined by tying a knot in a suture and testing it on a  
12 tensile --  
13 A. Yes.  
14 Q. -- testing machine?  
15 A. Yes.  
16 Q. How about knot tiedown? Is that --  
17 A. We didn't test for knot tiedown.  
18 Q. So you -- Before, you said knot strength and knot  
19 tiedown were the same thing.  
20 A. That's why I said that we tested for knot  
21 strength -- okay -- for -- of tying a knot. And I  
22 consider those the same things. So we didn't -- we didn't  
23 test specifically for tying soft tissue down. We tested  
24 the knot as tying a knot versus -- what the standard calls  
25 for and doing a pull test on it.

<p>1 Q. Let me back up to make sure this is clear. Knot 2 strength versus knot tiedown. In your mind, are they the 3 same thing or are they different?</p> <p>4 A. I'm not sure I understand your question. Say 5 that again.</p> <p>6 Q. Sure. Knot strength --</p> <p>7 A. Mmm-hmm (affirmative).</p> <p>8 Q. -- which I think you testified that you 9 understood to be tying a knot in a suture and pulling it 10 on a tensile machine -- tensile tester machine to 11 determine the strength at which the knot will break; 12 right?</p> <p>13 A. Yes.</p> <p>14 Q. Okay. Then there's another term called knot 15 tiedown, and I'm trying to understand whether, in your 16 mind, you think that's the same as knot strength or do you 17 use that term to mean something else?</p> <p>18 A. They're closely related.</p> <p>19 Q. And how are they related?</p> <p>20 A. When you have a knot tiedown, you've tied a knot. 21 The strength of the knot is going to affect the ability to 22 hold -- to approximate the tissue in the tiedown area that 23 you're talking about.</p> <p>24 Q. If the knot had a good tiedown or a bad tiedown, 25 what do you mean by that?</p>	<p>26 1 A. It's -- The tissue is here. The location the 2 surgeon wants it here. The suture loop as it is tied 3 moves the tissue into position.</p> <p>4 Q. Holds it there?</p> <p>5 A. Yes.</p> <p>6 Q. And what -- what biomechanical forces were you 7 referring to?</p> <p>8 A. Forces on the glenohumeral joint.</p> <p>9 Q. In a knot strength test, it's the forces are 10 being applied and generally in one direction; correct?</p> <p>11 A. Yes.</p> <p>12 Q. The biomechanical force that you are referring to 13 in this knot tiedown, the forces are coming from different 14 directions; right?</p> <p>15 A. Yes.</p> <p>16 Q. Okay. When you are referring to knot tiedown 17 then, you're referring to -- you're referring to it in a 18 sense as a strength?</p> <p>19 A. Are you finished? Is that the question?</p> <p>20 Q. Right.</p> <p>21 A. I don't believe -- Say it again then.</p> <p>22 Q. Sure. Knot tiedown, the way you're referring to 23 it, it's a strength then? It's kind of like -- because 24 knot strength would be measured in p.s.i.</p> <p>25 A. I said that's one of the attributes of it.</p>
<p>27 1 A. Its ability to approximate the tissue and hold it 2 in place through biomechanical forces.</p> <p>3 Q. So that's related to knot strength, but it's not 4 necessarily the same thing; is that the way you're using 5 the term?</p> <p>6 A. Yes.</p> <p>7 Q. The way I heard you describe knot tiedown was you 8 said the ability to approximate the tissue and hold it 9 into place through biomechanical forces.</p> <p>10 A. (Witness nods head affirmatively).</p> <p>11 Q. When you say ability to approximate the tissue, 12 what do you mean by that?</p> <p>13 A. Shift tissue in the position that the surgeon 14 would like for it to be on the bone.</p> <p>15 Q. Shift tissue; did you say?</p> <p>16 A. Yes.</p> <p>17 Q. S-H-I-F-T?</p> <p>18 A. Yes.</p> <p>19 Q. So the knot's moving the tissue?</p> <p>20 A. The suture is holding -- the suture loop with the 21 knot in it, is holding the tissue in the position that the 22 surgeon would like for it to be on bone.</p> <p>23 Q. That's taking the place of the tissue? When you 24 say approximate the tissue, how is it approximating 25 tissue?</p>	<p>29 1 That's not the total attribute of it. I mean it's to 2 approximate tissue into position is knot tiedown.</p> <p>3 Q. Well, what else would be included?</p> <p>4 A. I just told you. Approximate tissue, strength.</p> <p>5 Q. So the strength would -- I understand the --</p> <p>6 A. The size of the knot bundle. You know, there's 7 --</p> <p>8 Q. Size of the knot bundle?</p> <p>9 A. Yes.</p> <p>10 Q. What do you mean by that?</p> <p>11 A. How large the knot is once it has been tied and 12 cut.</p> <p>13 Q. So knot tiedown includes the size of the knot 14 bundle?</p> <p>15 A. Yes. You know, the knot tiedown -- I want to say 16 this -- that's not a term that we specifically use, so 17 it's a little bit foreign. I mean I don't -- I've never 18 had a surgeon ask me about knot tiedown.</p> <p>19 Q. Okay.</p> <p>20 A. So I didn't -- your -- I'm not sure where you're 21 going with this, but there's -- we did knot testing and we 22 did straight pull testing of the suture so that your knot 23 tiedown, I'm -- I'm not real sure what you're asking for 24 there. I --</p> <p>25 Q. Well --</p>

<p>1 A. What's the date on this?</p> <p>2 Q. The date on this is -- the last page is dated 3 November 4th, 2005.</p> <p>4 A. Okay. I want to quantify this then, because 5 you're talking about a time period after I worked for the 6 company, so when you -- when it says in here that I'm 7 familiar with these products, it would be at the time I 8 had left the company. And this is -- this was written 9 after I left the company. So I can't totally say that I 10 am familiar with those products under that.</p> <p>11 Q. So you would agree that you were familiar with 12 the state-of-the-art for surgical suture products as of 13 the date you left Arthrex?</p> <p>14 A. Define state-of-the-art, sir.</p> <p>15 Q. State-of-the-art? Well, the general -- You don't 16 have an understanding of what that means?</p> <p>17 A. I want to understand what you mean in the context 18 of this state-of-the-art.</p> <p>19 Q. Okay.</p> <p>20 A. I mean there's -- there's -- there's --</p> <p>21 Q. This is from Pearsalls, so I can't tell you 22 exactly what they mean, so ... Let me back up. When you 23 were --</p> <p>24 A. I was -- I was familiar with the competitive 25 products on the market and what we offered and how they</p>	<p>42 1. and tensile strength; right?</p> <p>2 A. Yes.</p> <p>3 Q. Didn't that come up in your testing?</p> <p>4 A. I don't recall.</p> <p>5 Q. What was your involvement in the development of 6 FiberWire?</p> <p>7 A. It was my idea.</p> <p>8 Q. When you say it was your idea, what do you mean 9 by that?</p> <p>10 A. I'll give you -- Would you like the story on how 11 FiberWire came about?</p> <p>12 Q. Sure.</p> <p>13 A. We were having issues from customers with the 14 Tevdek suture being low tensile strength as compared to 15 competitors' suture anchors with suture, primarily 16 Ethicon.</p> <p>17 Q. Ethibond?</p> <p>18 A. Ethibond. This was numerous complaints from 19 friendly surgeons, not -- not a massive amount of 20 complaints, but it was determined that the tensile 21 strength of the suture was not as good as the Ethicon 22 Ethibond suture.</p> <p>23 Q. When you say friendly, do you mean friendly to 24 Arthrex?</p> <p>25 A. Yes. And I had gotten a phone call from a Dr.</p>
<p>1 compared to the competitive products.</p> <p>2 Q. Okay. And that was as of the date you left 3 Arthrex?</p> <p>4 A. Yes.</p> <p>5 Q. Okay. And how long were you familiar with 6 Arthrex's suture products and the competitive suture 7 products that are in the marketplace?</p> <p>8 A. When we started marketing the product, the 9 sutures, until the time I left.</p> <p>10 Q. Okay. So sometime when Arthrex began selling the 11 suture from the supplier from New Mexico?</p> <p>12 A. Yes.</p> <p>13 Q. Okay. When Arthrex shifted from the Pearsalls 14 suture to the Tevdek suture, was there any consideration 15 to -- or for Arthrex designing its own suture?</p> <p>16 A. No.</p> <p>17 Q. Why not?</p> <p>18 A. Because we could find a suture OEM that was 19 available already. Why manufacture the suture when 20 there's a readily available source?</p> <p>21 Q. Now you said you tested for the Tevdek suture 22 before it was selected; right?</p> <p>23 A. Of course.</p> <p>24 Q. And then it came back after it was selected, the 25 response from surgeons was that it had low knot strength</p>	<p>43 1 Deberdino who was a surgeon at Fort Sam Houston, San 2 Antonio. His -- his comments were that he had tied three 3 knots the previous afternoon using the FASTak product of 4 Arthrex -- that's a glenoid labrum device -- and had broke 5 the knots on all three of them. And -- you know -- he 6 said it kind of jokingly. He said, "And I didn't even 7 work out the day before."</p> <p>8 And so he was tying to be nice about it, but 9 bottom line was your suture sucks. Okay?</p> <p>10 And so -- you know -- we're in a position where 11 we need to find a suture that will be competitive. I had 12 been to Pearsalls many times working on bioabsorbable 13 products. This was the time that you referred to earlier 14 where I said three to five, and was familiar with suture 15 manufacturing, the steps required to manufacture a suture.</p> <p>16 One of the trips there, Mr. Lyon had pointed out 17 to me a -- the other products they manufactured, which was 18 fishing line and silk used in decorated drapes. The 19 fishing line used a ultra-high molecular weight 20 polyethylene material that was very strong, and I -- at 21 some point, it was decided that we would try some of that 22 for a suture.</p> <p>23 I had Pearsalls, mainly through Brian, as being 24 the manufacturing person --</p> <p>25 Q. Brian Hallett?</p>

<p>1 A. That's correct -- make some Size 2 braided 2 material, send to me, and at the -- coincidentally, at the 3 same time, I had a Dr. Steve Burkhardt from San Antonio and 4 a Dr. Casey Chan, who is a R &amp; D guy in knot testing and 5 suture. They were -- they were at Arthrex at the time. 6 when this material showed up.</p> <p>7 We tested the material. The strength was 8 excellent. The knot slippage was very poor, would not 9 hold a knot.</p> <p>10 So at that point in time, it looked like we would 11 not be able to use an alternative material of ultra-high 12 molecular weight polyethylene because the slippage of the 13 material -- because of the slippage of the material tested 14 with Casey Chan -- Dr. Chan and Dr. Burkhardt. And so at 15 that point in time, the -- the product was -- was on hold.</p> <p>16 I was on a trip to Chicago to the national sales 17 meeting, and I had this idea of adding PET to the 18 ultra-high molecular weight polyethylene to enhance the or 19 reduce the knot slippage of the product. I sent an e-mail 20 to Dr. Steve Burkhardt and suggesting that since he was 21 familiar with the testing we had done very recently with 22 just the ultra-high molecular weight PE, of adding the 23 PET, and his -- I'll never forget the e-mail. He thought 24 that was a killer idea.</p> <p>25 And so I had asked then at that time for Brian</p>	46	<p>1 processed to make a braid.</p> <p>2 Q. Okay. And how many times were you over in 3 England?</p> <p>4 A. I told you already. Three to five.</p> <p>5 Q. Three to five.</p> <p>6 A. Approximate.</p> <p>7 Q. Is that total lifetime?</p> <p>8 A. That's an approximate number total lifetime, yes.</p> <p>9 Q. Have you been to other manufacturing facilities 10 for sutures?</p> <p>11 A. Jenzyme Tevdek.</p> <p>12 Q. And how many times have you been there?</p> <p>13 A. Once, I believe.</p> <p>14 Q. And when you were at Jenzyme Tevdek, did you see 15 the manufacturing processes for Tevdek?</p> <p>16 A. It was a dog and pony quick courtesy through the 17 facility.</p> <p>18 Q. So when you came up with the idea for using 19 ultra-high molecular weight polyethylene in a suture, did 20 you -- you say you are familiar with how sutures are made?</p> <p>21 A. I'm also a fisherman. There's -- you know -- 22 fishing line is -- uses ultra-high molecular weight 23 polyethylene as a material that's used for sport fishing, 24 very high strength.</p> <p>25 Pearsalls made fishing line. And so they had</p>	48
<p>1 Hallett to make me samples up of using those two materials 2 and -- and send to me. And we tested the materials, and 3 now we had a product that had superior tensile strength 4 and greater knot strength than any competitive product out 5 on the market.</p> <p>6 Q. Okay. If I could just back up to a couple of 7 points that you mentioned to make sure I understand what 8 happened here. The -- You said the idea began -- or I'm 9 sorry. Back up. You said when this idea came up, you had 10 already been to Pearsalls several times?</p> <p>11 A. Mmm-hmm (affirmative).</p> <p>12 Q. And you were familiar with --</p> <p>13 A. Yes.</p> <p>14 Q. And when this idea came up, you were familiar 15 with how sutures were manufactured?</p> <p>16 A. Yes.</p> <p>17 Q. Okay. And what did you mean by that?</p> <p>18 A. One of the products -- projects that I worked on 19 was a bioabsorbable suture similar to what Ethicon sells 20 as Panacryl, and the difference being this was 100 percent 21 PLLA material. The -- so we worked on this for about a 22 year -- I don't know the exact time -- with many trips 23 over to Pearsalls to change the construct of the yarn to 24 enhance the tensile properties of the material. And so at 25 that time, I became familiar with how a suture is</p>	47	<p>1 this material already available as a fishing line. So it 2 was an easy conversion -- you know -- conclusion, 3 conversion to say what if this is used as a suture 4 material, because ultra-high molecular weight polyethylene 5 is a totally inert material.</p> <p>6 Q. When you saw that Pearsalls had been using 7 ultra-high molecular weight polyethylene in fishing 8 line --</p> <p>9 A. Yes.</p> <p>10 Q. -- do you know how it was being used in fishing 11 line, what the construction was?</p> <p>12 A. No.</p> <p>13 Q. Was it a braided construction? Was it --</p> <p>14 A. I can't tell you for sure, sir.</p> <p>15 Q. You don't know?</p> <p>16 A. I wasn't interested in buying fishing line, so I 17 didn't look at the details of it.</p> <p>18 Q. So you had -- Sitting here today, you can't tell 19 me anything at all about how the fishing line that 20 Pearsalls was making with ultra-high molecular weight 21 polyethylene was constructed?</p> <p>22 A. It went through their manufacturing processes in 23 their company, but specifically how it was made, the 24 constructs, I have no idea or the size.</p> <p>25 Q. In other words, you have no idea if it was all</p>	49

<p>1 ultra-high molecular weight polyethylene or if it was 2 braided or -- 3 A. It's been too long ago. I can't tell you that. 4 Q. And your idea was to use the ultra-high molecular 5 weight polyethylene as a suture? 6 A. Yes. 7 Q. Okay. And you had Mr. Hallett make a Size 2, I 8 think you said? 9 A. Yes. 10 Q. Okay. Can you describe the construction of that 11 first -- 12 A. I don't remember now. It's been too long. 13 Q. Was it all ultra -- ultra-high molecular weight 14 polyethylene? 15 A. Initially, yes, as a test prototype material. 16 Q. Was it braided? 17 A. Yes. 18 Q. Was it an eight-carrier or a sixteen-carrier? 19 A. I don't remember. 20 Q. You said it was a Size 2 though? 21 A. Yes. 22 Q. So it was a Size 2 ultra-high molecular weight 23 polyethylene braided suture that did not have PET? 24 A. For the initial prototype material, that's 25 correct.</p>	<p>50 1 Q. Knot security test? 2 A. Yes. 3 Q. Was that the test we drew in Exhibit Number 421? 4 A. That's correct. 5 Q. Okay. And you said the strength was excellent, I 6 believe, of the initial prototype, but the knot slippage 7 was poor; is that right? 8 A. Yes. 9 Q. Okay. When you say the slippage was poor of the 10 initial prototype, what do you mean? 11 A. Less than the tensile strength capability of the 12 existing Arthrex product. 13 Q. So the knot slippage was less than the Tevdek 14 suture? 15 A. Yes. 16 Q. And it was -- knot slippage was such that it was 17 determined that the 100 percent ultra-high molecular 18 weight polyethylene suture prototype wasn't suitable to be 19 developed? 20 A. That's correct. Yes. 21 Q. Okay. Ultra-high molecular weight polyethylene, 22 you said the knot slippage was poor? 23 A. (Witness nods head affirmatively). 24 Q. Ultra-high molecular weight polyethylene, is that 25 a lubricious material?</p>
<p>1 Q. Okay. And it didn't have nylon or any other 2 material braided with it? 3 A. No. 4 Q. So the initial prototype was a ultra-high 5 molecular weight polyethylene braided suture prototype, if 6 you will? 7 A. Yes. Size 2. 8 Q. Size 2. And was the initial prototype, was it 9 coated? 10 A. I don't remember. 11 Q. Okay. Do you know if the initial prototype went 12 through any other manufacturing process like stretching or 13 heating, twisting? 14 A. I don't recall. 15 Q. Was the initial prototype 100 percent ultra-high 16 molecular weight polyethylene? 17 A. For the fourth time, yes. 18 Q. Okay. And you tested the initial prototype that 19 was 100 percent ultra-high molecular weight polyethylene 20 with Dr. Burkhardt and Dr. Chen? 21 A. Dr. Casey Chen, correct. 22 Q. Okay. And the test that you conducted with Dr. 23 Burkhardt and Dr. Chen on the ultra-high molecular weight 24 polyethylene was a knot strength test? 25 A. Knot security.</p>	<p>51 1 A. Yes. 2 Q. And was the knot slippage of this ultra-high 3 molecular weight polyethylene poor security because of the 4 lubricity of polyethylene? 5 A. Yes. 6 Q. Yes? 7 A. Yes. 8 Q. So then you came up with the idea to braid PET 9 with the ultra-high molecular weight polyethylene to 10 reduce the knot slippage? 11 A. Yes. 12 Q. And when you say knot slippage, we're referring 13 to this knot security test? 14 A. Yes. 15 Q. So are we using the terms knot slippage and knot 16 security interchangeably here? 17 A. You are, yes. 18 Q. In your testimony? 19 A. Yes. 20 Q. So the knot security of the 100 percent 21 ultra-high molecular weight polyethylene was poor, the 22 prototype; right? 23 A. Yes. 24 Q. And your idea was to add the PET and to improve 25 the knot security?</p>

<p>1 MR. SOFFEN: Objection; asked and answered.  2 You've asked him the same thing multiple times. But  3 you can answer.  4 A. I've lost count, it's been so many times, but the  5 answer again is yes.  6 Q. Okay. And Dr. Burkhardt said that was a killer  7 idea?  8 A. What was a killer idea?  9 Q. The killer idea was that your idea of adding  10 PED -- PET -- I'm sorry. I'll rephrase that question.  11 Did Dr. Burkhardt say that your idea to braid PET  12 with the ultra-high molecular weight polyethylene to  13 improve knot security was a killer idea?  14 A. Yes.  15 Q. Okay. And then you said you had Pearsalls  16 manufacture a prototype that had PET and ultra-high  17 molecular weight polyethylene braided?  18 A. Yes.  19 Q. And you tested that prototype?  20 A. Yes.  21 Q. And you said that that prototype had good knot  22 strength?  23 A. Correct.  24 Q. And the prototype of PET braided with ultra-high  25 molecular weight polyethylene had good knot security?</p>	<p>54  1 Q. I'm talking about the --  2 A. The second prototype with the PET?  3 Q. Correct.  4 A. Yes.  5 Q. The second prototype that had the coating on it?  6 A. Yes.  7 Q. And was that part of your initial idea, or was  8 that -- because I thought you said your initial idea was  9 to add the PET. Was it also to coat it, or was that  10 something that came later?  11 A. If you're going to market the product, it needs  12 the coating on it, sir.  13 Q. Okay. But the prototype that was manufactured  14 that you asked --  15 A. Most likely, it was coated, because it needed to  16 be as the final product would be marketed.  17 Q. You said most likely. Do you remember or you  18 don't remember whether the prototype that had the PET and  19 the ultra-high molecular weight polyethylene was coated?  20 A. I can't tell you for sure that it was at that  21 prototype stage.  22 Q. Okay. Was this prototype that you had -- after  23 you tested the prototype with PET with ultra-high --  24 A. Excuse me. I want to change that.  25 Q. Okay.</p>
<p>55  1 A. Yes.  2 Q. And the prototype of PET and ultra-high molecular  3 weight polyethylene braided together also had good tensile  4 strength?  5 A. Yes.  6 Q. And after you tested this second prototype, if  7 you will, of the PET braided with ultra-high molecular  8 weight polyethylene, was then the decision made to pursue  9 trying to commercially develop this idea?  10 A. Yes.  11 Q. Did you -- when you made -- Who made the decision  12 to go forward and try to commercialize this idea?  13 A. Myself and Reinhold, surgeons that we  14 collaborated with, marketing people. You know, it wasn't  15 just myself.  16 Q. Okay. Was this prototype that had the PET  17 braided with the ultra-high molecular weight polyethylene,  18 was it -- did it have a coating on it?  19 A. Yes.  20 Q. It did?  21 A. (Witness nods head affirmatively).  22 Q. And what was the coating?  23 A. I forget the name. It's like an MED2174s.  24 Q. That was on the prototype?  25 A. Which prototype are you referring to now?</p>	<p>55  1 A. I never got samples of constructions from  2 Pearsalls without a coating unless I specifically asked  3 for it not to be coated. So there's a very high  4 probability that the suture came as -- the second  5 prototype -- as coated.  6 Q. That was standard for them to coat it, in other  7 words?  8 A. Yes.  9 Q. Okay. So the initial prototype that was  10 ultra-high molecular weight polyethylene, did you ask for  11 that not to be coated?  12 A. No.  13 Q. So chances are that that one was coated?  14 A. Quite possibly.  15 Q. After you tested the prototype of PET and  16 ultra-high molecular weight polyethylene braided together,  17 did you believe that it would then work as a suture?  18 A. Yes.  19 Q. Okay. Is there anything else you think you  20 needed to do in order to determine whether it would work  21 as a suture?  22 A. Yes.  23 Q. What did you need to do?  24 A. Biocompatibility toxicity testing, bioburden  25 levels, all the design control GNP items that need to be</p>

<p>1 decitex?</p> <p>2 A. No. No, I can't remember that.</p> <p>3 Q. Do you recall evaluating any samples that had</p> <p>4 Dyneema 400 denier or higher?</p> <p>5 A. No.</p> <p>6 Q. Do you think you did or you just don't recall?</p> <p>7 A. I received -- I'm sure I received the samples.</p> <p>8 What I did with them, I don't recall.</p> <p>9 Q. Okay. How long -- how much before this letter do</p> <p>10 you think you came up with the idea to use the ultra-high</p> <p>11 molecular weight polyethylene with PET blended together?</p> <p>12 A. Whatever the Chicago National Sales Meeting was.</p> <p>13 The flight just before the start date would be the time</p> <p>14 that I came up with the idea. I don't know what that time</p> <p>15 is. I just remember the circumstance.</p> <p>16 Q. You say Chicago National Sales Meeting?</p> <p>17 A. That's correct.</p> <p>18 Q. Is that Arthrex National Sales Meeting?</p> <p>19 A. Yes.</p> <p>20 Q. Was that a meeting with all the Arthrex sales</p> <p>21 reps.?</p> <p>22 A. That's correct.</p> <p>23 Q. And it was sometime before the July -- It was the</p> <p>24 meeting before the July 10, 19 -- I'm sorry. The meeting</p> <p>25 where you came up with the idea was the meeting before the</p>	<p>66</p> <p>1 A. Yes.</p> <p>2 Q. It's not like they had a product that they could</p> <p>3 just give to you?</p> <p>4 A. No.</p> <p>5 Q. In your letter, you say you tested the samples of</p> <p>6 Dyneema. Do you see that?</p> <p>7 A. Yes.</p> <p>8 Q. And then you say, "Can you build a 25 percent</p> <p>9 Dyneema/75 percent polyester blend in Size 2 that is very</p> <p>10 flexible (like the existing suture or the Ethicon sample)</p> <p>11 and send it to me to test"; do you see that?</p> <p>12 A. Yes.</p> <p>13 Q. Does that Ethicon sample, does that refer to an</p> <p>14 Ethibond?</p> <p>15 A. Yes.</p> <p>16 Q. And you say, "If we get the" -- "If we can get</p> <p>17 this blend correct, we will have a terrific advancement in</p> <p>18 suture for our soft tissue anchors"; do you see that?</p> <p>19 A. Yes.</p> <p>20 Q. What did you mean by that?</p> <p>21 MR. SOFFEN: Objection; vague. It states what it</p> <p>22 states. What's the question?</p> <p>23 Q. Do you understand the question?</p> <p>24 A. I'm not sure what -- what you're asking.</p> <p>25 Q. I would like to know what you mean by in your</p>
<p>1 July 10th, 1998 date on this letter?</p> <p>2 A. Yes.</p> <p>3 Q. I show you DePuy Mitek Exhibit 324. Do you</p> <p>4 recognize Exhibit 324 as a letter from you to Mr. Hallett?</p> <p>5 A. I don't recall the letter, but I recognize my</p> <p>6 name and the contact person. But the specific</p> <p>7 circumstances of the letter, I don't remember.</p> <p>8 Q. Based on your prior testimony, is it then true</p> <p>9 that this letter was after you came up with the idea and</p> <p>10 after you evaluated the prototype?</p> <p>11 A. Yes. After I came up with the idea, yes.</p> <p>12 Q. Okay. Was this letter sent before or after you</p> <p>13 came up with the -- I'm sorry. Was this November 16th,</p> <p>14 1998 letter sent before or after you came up with the --</p> <p>15 Sorry. I will rephrase the question.</p> <p>16 Was the November 16th, 1998 letter, Exhibit 324,</p> <p>17 sent before or after you evaluated the prototype of</p> <p>18 ultra-high molecular weight polyethylene braided with PET?</p> <p>19 A. I don't recall.</p> <p>20 Q. When you had the prototype of PET and ultra-high</p> <p>21 molecular weight polyethylene made, do you know if</p> <p>22 Pearsalls specifically made that or if they just pulled it</p> <p>23 off their line from something else?</p> <p>24 A. I'm sure they made it.</p> <p>25 Q. They specifically made it?</p>	<p>67</p> <p>1 letter when you said, "If we can get this blend correct."</p> <p>2 You asked them for a 25 percent Dyneema/75 percent</p> <p>3 polyester blend in Size 2 that's very flexible. And then</p> <p>4 you said, "If we can get this blend correct, we will have</p> <p>5 a terrific advancement."</p> <p>6 What did you mean by "If we can get this blend</p> <p>7 correct"?</p> <p>8 A. The optimization of the two materials. If you</p> <p>9 had the knot strength, loop security, and tensile</p> <p>10 strength, as well as the tactile feel of the suture all</p> <p>11 superior to what was on the market, then it would be a</p> <p>12 superior product.</p> <p>13 Q. Wait a second. You said optimization of two</p> <p>14 materials.</p> <p>15 A. (Witness nods head affirmatively).</p> <p>16 Q. At this point in time, November 1998, were you</p> <p>17 trying to vary the amount and type of the Dyneema and</p> <p>18 polyester in the braid in order to get the best</p> <p>19 properties?</p> <p>20 A. During -- during the -- during that period of</p> <p>21 time, yes.</p> <p>22 Q. So you were balancing off the properties of each</p> <p>23 material to try to get the optimum properties --</p> <p>24 A. Tensile strength.</p> <p>25 Q. To get the optimum tensile strength?</p>

<p>1 A. (Witness nods head affirmatively).</p> <p>2 Q. What about knot security?</p> <p>3 A. Yes.</p> <p>4 Q. Okay. So you were varying the amount and type of 5 the materials to get the optimum knot security, optimum 6 tensile strength?</p> <p>7 A. Yes.</p> <p>8 Q. Any other properties? Knot tiedown?</p> <p>9 A. The slideability of the knot, the tactile feel in 10 the surgeon's hands of the material.</p> <p>11 Q. So you were varying type and proportion of the 12 materials to optimize all these properties in the product?</p> <p>13 A. Yes.</p> <p>14 Q. Were the product samples that were being made at 15 this time in November of 1998, around this time, were they 16 being made on a carrier braid machine?</p> <p>17 A. Yes.</p> <p>18 Q. I show you DePuy Mitek Exhibit 325. It's a 19 letter dated November 16th, 1998 from Mr. Hallett to you. 20 Do you see that?</p> <p>21 A. Yes.</p> <p>22 Q. Do you recall receiving this letter?</p> <p>23 A. No.</p> <p>24 Q. It says -- Mr. Hallett says in the letter, 25 "Please find enclosed a matrix of information of the</p>	70	<p>1 Q. Do you see under the yarns the first one is 2 Dyneema?</p> <p>3 A. Yes.</p> <p>4 Q. And is it has a DT number. Do you see that?</p> <p>5 A. DT.</p> <p>6 Q. Dt-no. Does that stand for DT number?</p> <p>7 A. Where -- where do you see DT?</p> <p>8 Q. The second column.</p> <p>9 A. At the top as the heading, yes.</p> <p>10 Q. Okay. Are you familiar that Pearsalls uses the 11 terminology DT number for samples?</p> <p>12 A. I don't recall what they use.</p> <p>13 Q. You don't recall? Okay.</p> <p>14 Q. Was it the first sample -- Do you see where the 15 first one is Dyneema and the second ones are Polys, the 16 second through fourth are Poly/Dyneema? Do you see that?</p> <p>17 A. Yes.</p> <p>18 Q. Was the first sample of yarn here all Dyneema?</p> <p>19 A. Evidently.</p> <p>20 Q. Do you see in the second through the fourth yarns 21 were a braided blend of Polyethylene and Dyneema?</p> <p>22 A. Yes.</p> <p>23 Q. Do you see the straight pull column?</p> <p>24 A. Yes.</p> <p>25 Q. I'm sorry. I may have misspoke.</p>	72
<p>1 samples that you took with you on your visit to Pearsalls. 2 I will endeavor to proceed with the existing trial to 3 match the US2 Excel Braid made by Ethicon, in polyester 4 construction." Do you see that?</p> <p>5 A. Yes.</p> <p>6 Q. Did you pick up the samples from Pearsalls that 7 are mentioned in this --</p> <p>8 A. I don't recall.</p> <p>9 Q. Do you recall whether they were actually -- Do 10 you recall going over to Pearsalls and having them 11 actually make samples while you were there?</p> <p>12 A. Yes.</p> <p>13 Q. And were these samples -- These aren't samples 14 they pulled off the line? These are samples where they 15 took yarns and braided them according to what you guys 16 were considering?</p> <p>17 A. Repeat the question again.</p> <p>18 Q. Sure. I'm just trying to get the sense of 19 whether the samples that you picked up while you were at 20 Pearsalls that you saw being made, were they -- was it an 21 existing product they were picking up off the product 22 line, or was this -- you know -- yarns that were selected 23 and braided and going through the manufacturing process 24 that you particularly picked out?</p> <p>25 A. The latter.</p>	71	<p>1 The second through fourth yarns that are listed, 2 the Poly/Dyneema, is that -- are they Polyester and 3 Dyneema?</p> <p>4 A. Yes.</p> <p>5 Q. Not polyethylene and Dyneema?</p> <p>6 A. It's ultra-high molecular weight polyethylene and 7 PET.</p> <p>8 Q. Okay. Do you see the column straight pull?</p> <p>9 A. Yes.</p> <p>10 Q. Do you know what that means?</p> <p>11 A. Testing that they did in their lab with their 12 tensile test machine in kilograms.</p> <p>13 Q. Is that with a knot or without a knot?</p> <p>14 A. That's without a knot.</p> <p>15 Q. Okay. And do you see how the Dyneema one was 16 23.12 kilograms?</p> <p>17 A. Yes.</p> <p>18 Q. And Poly/Dyneemas were on the order of 34 to 36 19 kilograms?</p> <p>20 A. Yes.</p> <p>21 Q. Do you know why the difference in strength 22 between the Dyneema one and the other ones?</p> <p>23 A. You can't tell by looking at this report why 24 there's a difference.</p> <p>25 Q. And you don't remember?</p>	73

<p>1 Q. Okay. I show you DePuy Mitek Exhibit 164. Do 2 you recognize Exhibit 164 as a letter from Mr. Hallett to 3 you?</p> <p>4 A. Yes.</p> <p>5 Q. And did you receive Exhibit 164 on October 19th, 6 2000?</p> <p>7 A. Evidently so.</p> <p>8 Q. It says the subject is Polyester-Dyneema Braid. 9 Do you see that?</p> <p>10 A. Yes.</p> <p>11 Q. And then it says, "Dear Don: Please find 12 enclosed four DT trials samples for your inspection. 13 These have been made using Polyester/Dyneema mixed either 14 in the core -- I'm sorry -- mixed either in the cover or 15 straight core to match US2. I have set up below a matrix 16 of how each was made and the results for your 17 information." Do you see that?</p> <p>18 A. Yes.</p> <p>19 Q. And the first sample is the DT PA23 sample. Do 20 you see that?</p> <p>21 A. Yes.</p> <p>22 Q. And if you go down to the cover, it was 16 23 carriers in use each with one end of 138 d'tex Polyester 24 per carrier. Do you see that?</p> <p>25 A. Mmm-hmm (affirmative).</p>	78	<p>1 use, 16 carriers with one end of 113 polyester per 2 carrier. Do you see that?</p> <p>3 A. Yes.</p> <p>4 Q. So the DT PA27 had a polyester braided cover; 5 right?</p> <p>6 A. Yes.</p> <p>7 Q. Okay. Now if you look at the knot pull strength 8 of each, of the DT PA23, which was a polyester cover, had 9 a 10.35 at the finish stage of knot pull?</p> <p>10 A. Yes.</p> <p>11 Q. And the DT PA25 had a knot pull at the center 12 stage of 11.95?</p> <p>13 A. Yes.</p> <p>14 Q. Do you know what the finish stage is?</p> <p>15 A. Yes.</p> <p>16 Q. What is the finish stage?</p> <p>17 A. After coating.</p> <p>18 Q. Okay. And the DT PA26 had a knot pull of 12.87; 19 do you see that?</p> <p>20 A. Yes.</p> <p>21 Q. And the DT PA27 had a knot pull at finish of 22 8.04. Do you see that?</p> <p>23 A. Yes.</p> <p>24 Q. So if you look back and look at the numbers, the 25 first one, the DT PA23 was the polyester cover braid, and</p>	80
<p>1 Q. So the first sample of DT PA23 had a cover that 2 was all polyester; right?</p> <p>3 A. Yes.</p> <p>4 Q. And is this letter part of the development of 5 FiberWire? It was sent to you in connection with the 6 development of FiberWire?</p> <p>7 A. Yes.</p> <p>8 Q. If you turn over to the next page, the second 9 sample is DT PA25. And if you look at the cover 10 construction, it was 16 carriers in use, 8 carriers with 11 one end of 113 polyester, 8 carriers with one end of 110 12 Dyneema. Do you see that?</p> <p>13 A. Yes.</p> <p>14 Q. So the PA25 had a cover that was a 15 Polyester/Dyneema blend?</p> <p>16 A. Correct.</p> <p>17 Q. The DT PA26, the construction of that cover was 18 16 carriers in use, 8 carriers with one end of 113 19 polyester, 8 carriers with one end of 110 Dyneema. Do you 20 see that?</p> <p>21 A. Yes.</p> <p>22 Q. So the DT PA26 had a Polyester/Dyneema braid 23 construction in the cover?</p> <p>24 A. Correct.</p> <p>25 Q. And the DT PA27 had a cover of 16 carriers in</p>	79	<p>1 its knot strength at finish was less than the DT PA25 and 2 DT PA26; correct?</p> <p>3 A. Yes.</p> <p>4 Q. And DT PA27 was also a polyester cover, and its 5 knot strength at finish stage was less than that of DT 6 PA25 and 26; right?</p> <p>7 A. Yes.</p> <p>8 Q. Do you know why the DT PA23 and PA 27 samples had 9 lower knot pull strength at the finish stage than DT PA25 10 and DT PA26?</p> <p>11 A. Because there was no Dyneema in the jacket or 12 cover.</p> <p>13 Q. And you say that the finish stage was after 14 coating, so all these products had the -- I'm sorry -- so 15 you said the finish stage was after coating, so the DT 16 PA23, 25, 26, and 27 all had coating on it?</p> <p>17 A. Yes.</p> <p>18 Q. They had the same coating?</p> <p>19 A. Yes.</p> <p>20 Q. They went through the same coating processes?</p> <p>21 A. Yes.</p> <p>22 Q. If you look at the d'tex of the Dyneema yarn that 23 was used in these prototypes, it was -- in the cover, the 24 DT PA25 had 110 Dyneema, and the DT PA26 also had 110 25 Dyneema in the cover? Do you see that?</p>	81

<p>1 Q. You're sure you did?</p> <p>2 A. Yes.</p> <p>3 Q. And what did you review it for?</p> <p>4 A. Accuracy, to be sure it covered as much of a claim area as possible.</p> <p>6 Q. Okay. Do you recall having any discussions with an attorney that this patent -- patent Exhibit 423 was not accurate?</p> <p>9 A. I don't recall that, no.</p> <p>10 Q. Do you recall asking an attorney to change anything in Exhibit 423 and having them say no?</p> <p>12 A. I don't know. I don't recall.</p> <p>13 Q. And do you see how on the front of Exhibit 423, if you look on the first page, it says the Agent, Attorney or Firm, do you see where it says Dickstein, Shapiro, Morin &amp; Oshinsky, LLP; do you see that?</p> <p>17 A. Yes.</p> <p>18 Q. Do you recall working with attorneys from Dickstein, Shapiro, Morin &amp; Oshinsky in preparing this application?</p> <p>21 A. Yes.</p> <p>22 Q. Do you recall working with Mr. Soffen in preparing this patent application that became the '423 patent?</p> <p>25 A. Yes.</p>	<p>102</p> <p>1 stronger than ordinary surgical suture, does not have 2 acceptable knot tiedown characteristics for use in 3 surgical applications." Do you see that?</p> <p>4 A. Yes.</p> <p>5 Q. Do you agree with that?</p> <p>6 A. Yes.</p> <p>7 Q. Do you see the reference to knot tiedown?</p> <p>8 A. Yes.</p> <p>9 Q. Is that reference to knot tiedown what we referred to this morning as knot tiedown as you described it?</p> <p>12 A. It's one of the items we referred to, yes.</p> <p>13 Q. And how you defined it this morning, is -- are you using that same definition here?</p> <p>15 A. Yes.</p> <p>16 Q. Okay. If you go on the front page of this document, it notes Patent Documents -- U.S. Patent Documents References Cited; do you see that?</p> <p>19 A. Yes.</p> <p>20 Q. And there's a section of Foreign Patent Documents and Other Publications. Do you see that?</p> <p>22 A. Mmm-hmm (affirmative). Yes.</p> <p>23 Q. Do you recall whether you asked for any fishing line products to be disclosed to the patent office that used ultra-high molecular weight polyethylene?</p>
<p>1 Q. Is Mr. Soffen generally the person you've worked with in preparing patent -- patent applications?</p> <p>3 A. He's one of them, yes.</p> <p>4 Q. Okay. And how about Mr. McGee?</p> <p>5 A. Yes.</p> <p>6 Q. Okay. Do you have an understanding that in providing a description of your invention, that the invention should be sufficiently described so that someone skilled in the art could make it?</p> <p>10 A. Yes.</p> <p>11 Q. Okay. If I could turn to paragraph -- the text beginning on Page ARM 286, the second paragraph, the description of the related art. Do you see that?</p> <p>14 A. Yes.</p> <p>15 Q. It says, "Suture strength is an important consideration in surgical suture material." Do you agree with that?</p> <p>18 A. Yes.</p> <p>19 Q. It says, "One of the strongest materials currently formed into elongated strands is an ultra-high molecular long chain weight polyethylene typically used for fishing lines and the like which is sold under the trade names Dyneema or Spectra." Do you agree with that?</p> <p>24 A. Yes.</p> <p>25 Q. It says, "However, this material, while much</p>	<p>103</p> <p>105</p> <p>1 A. Don't recall.</p> <p>2 Q. Go to the Detailed Description of the Preferred Embodiments. Do you see that? It begins on Column 2.</p> <p>4 A. Yes.</p> <p>5 Q. It says, "Referring to FIG. 1, a scanning electron micrograph of a length of suture 2 according to the present invention is shown."</p> <p>8 A. Excuse me. I'd like to interrupt you --</p> <p>9 Q. Sure.</p> <p>10 A. -- on one of your comments. I want to be sure I get that correct. The -- When you said whether I specifically asked for a fishing line or fishing line patents to be looked at --</p> <p>14 Q. I didn't say patent. I said products.</p> <p>15 A. Products? The key word would have been put in for the materials used, and if those then had a hit, if you will, with the fishing line, then that patent would have come up.</p> <p>19 Q. Right. But I'm just talking about products like -- that were on the market like fishing line products.</p> <p>22 A. No. No. That was --</p> <p>23 Q. Like the one Pearsalls made.</p> <p>24 A. No, we didn't look at Spider Wire or other fishing lines.</p>



# **BROOKSTEIN DECLARATION**

## **EXHIBIT 4**



US006716234B2

**(12) United States Patent**  
**Grafton et al.**

**(10) Patent No.:** US 6,716,234 B2  
**(45) Date of Patent:** Apr. 6, 2004

**(54) HIGH STRENGTH SUTURE MATERIAL**

**(75) Inventors:** R. Donald Grafton, Naples, FL (US); D. Lawson Lyon, Exeter (GB); Brian Hallet, Taunton (GB)

**(73) Assignee:** Arthrex, Inc., Naples, FL (US)

**(\*) Notice:** Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 5 days.

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**(51) Int. Cl.:** A61L 17/04

**(52) U.S. Cl.:** 606/228

**(58) Field of Search:** 606/228

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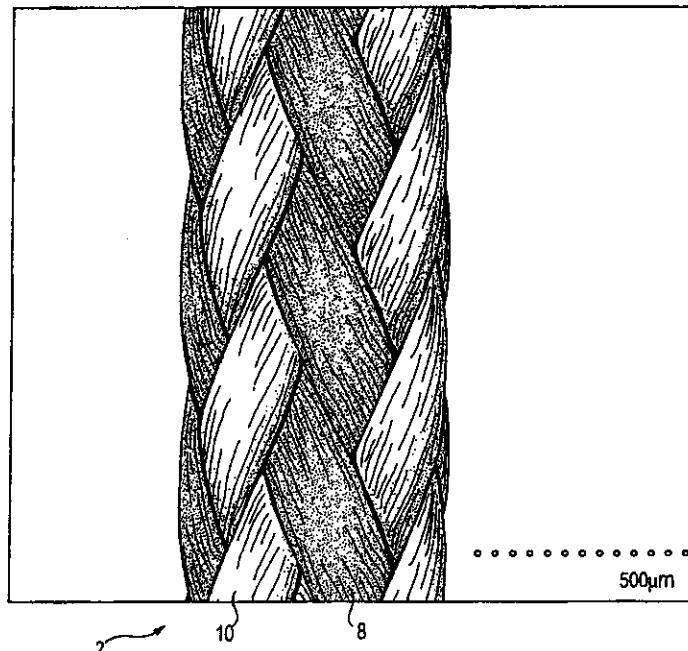
**Primary Examiner:** David O. Reip

**(74) Attorney, Agent, or Firm:** Dickstein Shapiro Morin & Oshinsky, LLP

**(57) ABSTRACT**

A high strength abrasion resistant surgical suture material with improved tie down characteristics. The suture features a multifilament cover formed of braided strands of ultra high molecular weight long chain polyethylene and polyester. The cover surrounds a core formed of twisted strands of ultrahigh molecular weight polyethylene. The suture, provided in a #2 size, has the strength of #5 Ethibond, is ideally suited for most orthopedic procedures, and can be attached to a suture anchor or a curved needle.

9 Claims, 2 Drawing Sheets

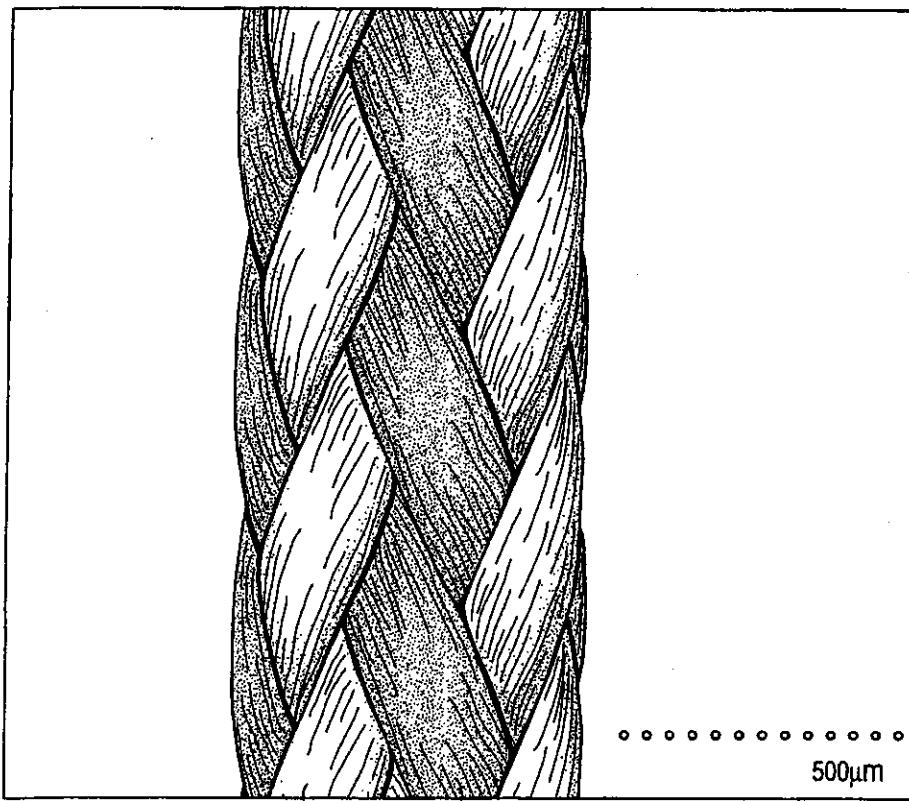


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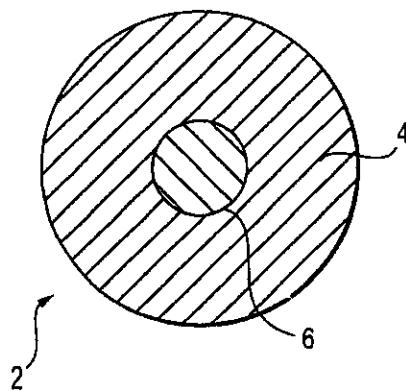
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**FIG. 1**



**FIG. 2**

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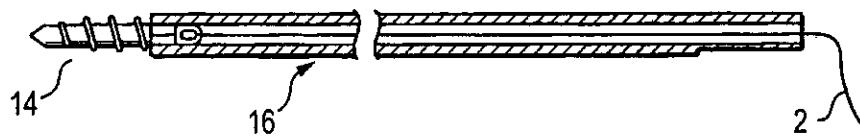


FIG. 3

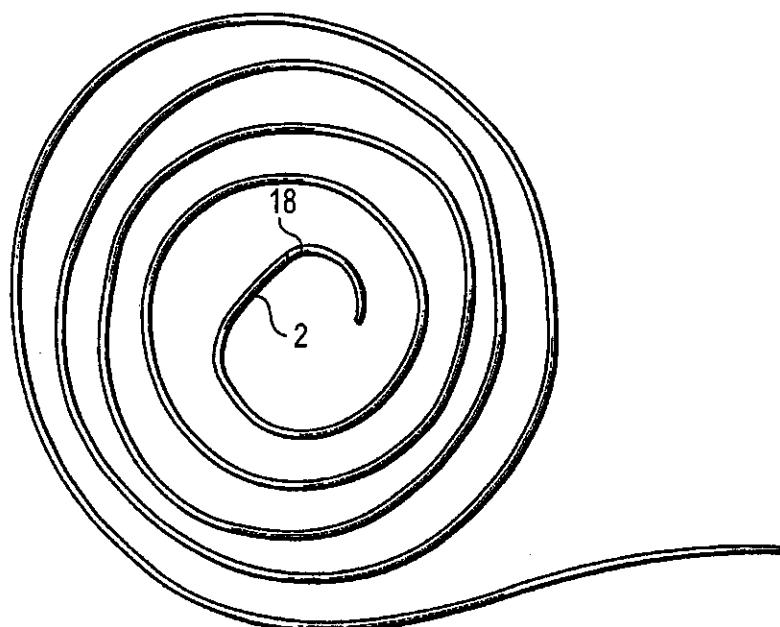


FIG. 4A

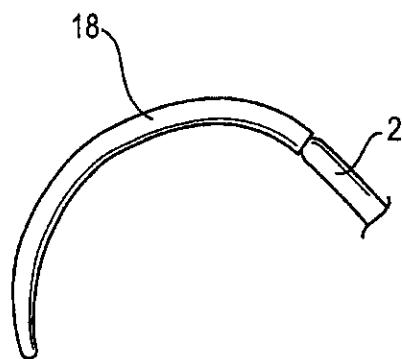


FIG. 4B

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## HIGH STRENGTH SUTURE MATERIAL

## BACKGROUND OF THE INVENTION

## 1. Field of the Invention

The present invention relates to high strength surgical suture materials, and more particularly to braided suture blends of ultrahigh molecular weight polyethylene and polyester having high strength and excellent tie down characteristics.

## 2. Description of the Related Art

Suture strength is an important consideration in any surgical suture material. One of the strongest materials currently formed into elongated strands is an ultrahigh molecular long chain weight polyethylene, typically used for fishing line and the like, which is sold under the trade names Dyneema or Spectra. However, this material, while much stronger than ordinary surgical suture, does not have acceptable knot tie down characteristics for use in surgical applications.

## SUMMARY OF THE INVENTION

The present invention advantageously provides a high strength surgical suture material with improved tie down characteristics. The suture features a braided cover made of a blend of ultrahigh molecular weight long chain polyethylene and polyester. The polyethylene provides strength. The polyester provides improved tie down properties.

The preferred suture includes a multifilament cover formed of a plurality of fibers of ultrahigh molecular weight polyethylene braided with fibers of polyester. The cover surrounds a core of twisted fibers of ultrahigh molecular weight polyethylene.

Preferably, the ultrahigh molecular weight polyethylene includes about 60% of the cover fibers, with polyester making up about 40% of the cover filaments. The core comprises about 30% of the suture, the cover making up about 70%. As an enhancement, the suture is provided with a coating on the cover, as is known in the prior art. The suture can be packaged ready for use attached to a suture anchor.

Ultrahigh molecular weight polyethylene fibers suitable for use in the present invention are marketed under the Dyneema trademark by Toyo Boseki Kabushiki Kaisha.

The suture of the present invention advantageously has the strength of Ethibond #5 suture, yet has the diameter, feel and tie ability of #2 suture. As a result, the suture of the present invention is ideal for most orthopedic procedures such as rotator cuff repair, achilles tendon repair, patellar tendon repair, ACL/PCL reconstruction, hip and shoulder reconstruction procedures, and replacement for suture in anchors.

Other features and advantages of the present invention will become apparent from the following description of the invention which refers to the accompanying drawings.

## BRIEF DESCRIPTION OF THE DRAWING(S)

FIG. 1 is a copy of a scanning electron micrograph of a length of suture according to the present invention.

FIG. 2 is a schematic cross section of a length of suture according to the present invention.

FIG. 3 is an illustration of the suture of the present invention attached to a suture anchor.

FIGS. 4A and 4B show the suture of the present invention attached to a half round, tapered needle.

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## DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring to FIG. 1, a scanning electron micrograph of a length of suture 2 according to the present invention is shown. Suture 2 is made up of a cover 4 and a core 6 surrounded by the cover. See FIG. 2. Strands of ultrahigh molecular weight polyethylene (UHMWPE) 8, sold under the tradename Dyneema or Spectra, and strands of polyester 10 are braided together to form the cover 4. The core is formed of twisted UHMWPE.

Details of the present invention will be described further below in connection with the following examples:

## EXAMPLE 1

## USP Size 5 (EP size 7)

Made on a 16 carrier Hobourns machine, the yarns used in the braided cover are polyester type 712 and Dyneema SK65. The cover is formed using eight carriers with one end of 190 d'tex polyester per carrier, and eight carriers with one end of 220 d'tex Dyneema per carrier. The core is formed of Dyneema using one end of 440/1/3 twisted 10 tpi "z" and 7 tpi "s" (core is not steam set). Picks per inch (PPI)=36. In forming the suture, the percent cover is 71.31, while the percent of the core is 28.69. Runnage is 1991 meters per kilo.

Of the overall suture, the polyester in the cover (8 carriers $\times$ 190 d'tex=1520 d'tex) makes up 33.04% of the suture, and the Dyneema in the cover (8 carriers $\times$ 220 d'tex=1760 dtex) makes up 38.76% of the suture. The Dyneema core (3 carriers $\times$ 440 d'tex=1320 d'tex) is 28.69% of the suture.

## EXAMPLE 2

## USP Size 2

The suture is 38.09% polyester, 61.91% UHMWPE, or about 40% polyester and about 60% UHMWPE.

The examples above are for size 2 and size 5 sutures. In the making of various sizes of the inventive suture, different decitex values and different PPI settings can be used to achieve the required size and strength needed. In addition, smaller sizes may require manufacture on 12 carrier machines, for example. The very smallest sizes are made without a core. Overall, the suture may range from 5% to 90% ultrahigh molecular weight polymer (Dyneema), with the balance formed of polyester.

The suture is preferably coated with a silicon based coating to fill in voids and provide optimum run down.

The Dyneema component of the present invention provides strength, and the polyester component is provided to improve tie ability and tie down characteristics. However, it has been found that the Dyneema provides an unexpected advantage of acting as a cushion for the polyester fibers, which are relatively hard and tend to damage each other. The Dyneema prevents breakage by reducing damage to the polyester when the suture is subjected to stress.

According to an alternative embodiment of the present invention, a partially bioabsorbable suture is provided by blending a high strength material, such as UHMWPE fibers, with a bioabsorbable material, such as PLLA or one of the other polylactides, for example. Accordingly, a suture made with about 10% Dyneema blended with absorbable fibers would provide greater strength than existing bioabsorbable suture with less stretch. Over time, 90% or more of the suture would absorb, leaving only a very small remnant of the knot.

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In one method of using the suture of the present invention, the suture 2 is attached to a suture anchor 14 as shown in FIG. 3 (prepackaged sterile with an inserter 16), or is attached to a half round, tapered needle 18 as shown in FIGS. 4A and 4B.

Although the present invention has been described in relation to particular embodiments thereof, many other variations and modifications and other uses will become apparent to those skilled in the art. It is preferred, therefore, that the present invention be limited not by the specific disclosure herein, but only by the appended claims.

What is claimed is:

1. A suture filament suitable for use as a suture or ligature comprising:

a cover formed of a plurality of braided fibers of ultrahigh molecular weight polyethylene and polyester; and

a core of twisted ultrahigh molecular weight polyethylene surrounded by the cover.

2. The suture filament of claim 1, wherein the ultrahigh molecular weight polyethylene comprises about 60% of the braided fibers.

3. The suture filament of claim 1, wherein the polyester comprises about 40% of the braided fibers.

4. The suture filament of claim 1, wherein the core comprises about 30% of the filament.

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5. The suture filament of claim 1, wherein the cover comprises about 70% of the filament.

6. The suture filament of claim 1, further comprising a coating disposed on the cover.

7. The suture filament of claim 1, wherein the polyester is non-absorbable.

8. A suture assembly comprising:

a suture having a multifilament cover formed of a plurality of braided fibers of ultrahigh molecular weight polyethylene and fibers of polyester;

a core formed of twisted fibers of ultrahigh molecular weight polyethylene; and

a suture anchor attached to the suture.

9. A suture assembly comprising:

a suture having a multifilament cover formed of a plurality of braided fibers of ultrahigh molecular weight polyethylene and fibers of polyester;

a core formed of twisted fibers of ultrahigh molecular weight polyethylene; and

a half round, tapered needle attached to the suture.

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